



Kaiser Foundation Health Plan of Washington

**Clinical Review Criteria
Advanced Bronchoscopy Techniques**

- Endobronchial ultrasound
- Electromagnetic navigation

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	<p>Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Endobronchial Ultrasound" for medical necessity determinations. Use the Non-Medicare criteria below.</p> <p>Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Electromagnetic Navigation Bronchoscopy (ENB)" for medical necessity determinations. Use the Non-Medicare criteria below.</p>

For Non-Medicare Members⁴

Service	Criteria	
Endobronchial Ultrasound <i>(common CPT 31652, 31653, 31654, C7512)</i>	Kaiser Permanente has elected to use the Endobronchial Ultrasound (A-1049) MCG* Care Guideline for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under <i>Quick Access</i> .	
Electromagnetic Navigation <i>(common CPT 31627, 31654)</i>	Biopsy of Peripheral Lesions	Electromagnetic navigation is covered when performed with biopsy of peripheral lesions.
	Fiducial Marker Placement	Electromagnetic navigation is not covered when used for Fiducial Marker Placement as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Flexible bronchoscopy (FB) is a minimally invasive procedure that is used for the diagnosis and treatment of lung cancer. Research suggests that the sensitivity of FB is approximately 88% for diagnosing central lesions and 78% for diagnosing peripheral lesions (most commonly defined as lesions that are not visible beyond the visual segmental bronchi). However, the sensitivity of FB is dependent on lesion size. FB does not perform as well for smaller peripheral lesions. It has been estimated that for peripheral lesions less than 2 cm in diameter the sensitivity of FB is approximately 34% (Rivera 2007).

Electromagnetic navigation bronchoscopy (ENB) is a relatively new bronchoscopic tool that combines CT-generated virtual bronchoscopy and electromagnetic tracking of a steerable probe to allow physicians to perform biopsy of peripheral lesion that are not accessible through conventional bronchoscopy. It has also been suggested that mediastinal lymph nodes can be biopsied using ENB. Other uses of ENB include implantation of fiducial markers for radiotherapy, implantation of brachytherapy seeds or catheters, and dye marker placement for surgical resection.

Several ENB systems have received FDA approval. ENB using the superDimensions I Logic™ System (superDimensions, Inc. Minneapolis, MN) is performed in three phases – planning, registration, and navigation and biopsy (Bechara 2011, Schwartz 2010).

1. Planning: A three-dimensional image of the patient's lungs with anatomical landmarks is constructed using previously taken CT scans and proprietary software.
2. Registration: The steerable navigation catheter is inserted through the bronchoscope. The three-dimensional image with anatomical landmarks created in the planning phase is viewed and correlated with the actual image from the video bronchoscope. The position of each landmark is marked using a foot pedal.
3. Navigation and biopsy: The steerable catheter is used to navigate to the lesion. The location of the catheter's tip is displayed on the CT images. Once the catheter reaches the target, it is locked in place, and the working guide is retracted. Once the catheter is in place, any endoscopic tool can be inserted through the channel. This includes transbronchial forceps to biopsy the lesion or guide wire for the placement of fiducial markers.

Medical Technology Assessment Committee (MTAC)**Electromagnetic Navigation Bronchoscopy****08/20/2012: MTAC REVIEW**

Evidence Conclusion: Diagnostic yield A recent RCT that included 118 subjects with evidence of peripheral lung lesions or solitary primary nodules on CT evaluated the diagnostic yield of endobronchial ultrasound (EBUS), electromagnetic navigation bronchoscopy (ENB), and combined EBUS/ENB. Results from this study suggest that combined EBUS/ENB improves diagnostic yield compared to either method alone. The pneumothorax rate was 5% in the EBUS and ENB alone groups and 8% in the combined group. There was no significant difference in pneumothorax rate between the three groups (Eberhardt 2007).

Diagnostic yield (Eberhardt 2007)		
EBUS	ENB	Combined
69%	59%	88%

A recent meta-analysis also evaluated the diagnostic yield of different guided bronchoscopy methods. Results from this meta-analysis suggest that the diagnostic yield of ENB is approximately 67%. Results from this meta-analysis should be interpreted with caution as the majority of the studies included in the meta-analysis were small

case series (Wang Memoli 2012). Since the meta-analysis two additional case-series were identified. The first case-series included 112 subjects and evaluated the diagnostic yield of ENB combined with rapid on-site cytopathologic evaluation (ROSE). Overall, the diagnostic yield in this study was 84%. In lesions less than 2 cm, the diagnostic yield was 75.6% and 89.6% in lesions greater than 2 cm. There were two cases (1.8%) of pneumothorax (Lamprecht 2012). The second case-series included 101 subjects and also evaluated the diagnostic yield of ENB combined with ROSE. The diagnostic yield from this study was 85%. There were 6 cases (5.8%) of pneumothorax (Pearlstein 2012). **Fiducial marker placement** A small observational study evaluated the transcutaneous placement of fiducial markers using either CT or fluoroscopic guidance (N=15) or transbronchial placement using ENB (N=8) in patient with small, early-stage, non-small cell lung cancer. Pneumothorax occurred in 8 patients (53%) who underwent transcutaneous placement and no patients who underwent transbronchial placement. The fiducial markers did not show substantial migration during the course of treatment for either method (Kupelian 2007). Conclusion: Diagnostic yield: Results from a RCT, a meta-analysis of mainly small case-series, and two case-series suggests that the overall diagnostic yield of ENB is approximately 59 to 85%.

Safety: The pneumothorax rate in the studies ranged from 1.8 to 8%.

Fiducial marker placement: There is insufficient evidence to determine the safety and clinical utility of ENB for the placement of fiducial markers.

Articles: Several small observational studies, a randomized controlled trial (RCT), and a meta-analysis were identified that evaluated the use of ENB for diagnosing lung cancer. The meta-analysis and the RCT were selected for review. A few small observational studies were identified that evaluated fiducial marker placement using ENB. The number of patients receiving ENB for the placement ranged from 1 to 12. Due to the small sample size none of these studies were selected for review. A summary of the results from one of the more recent studies is presented below. The following articles were selected for review: Eberhardt R, Anantham D, Ernst A, Feller-Kopman D, Herth F. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. *Am J Respir Crit Care Med.* 2007;176:36-41. See [Evidence Table](#). Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-Analysis of Guided Bronchoscopy for the Evaluation of the Pulmonary Nodule. *Chest.* 2011. See [Evidence Table](#).

The use of ENB for diagnosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of ENB for fiducial marker placement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Biopsy of peripheral lesions, Fiducial marker placement

CPT Codes	Description
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with computer-assisted, image-guided navigation (list separately in addition to code for primary procedure)
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])

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Endobronchial Ultrasound

CPT Codes	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])
C7512	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s), including fluoroscopic guidance when performed

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012 ^{MDCRPC} , 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/03/2014 ^{MPC} , 02/03/2015 ^{MPC} , 12/01/2015 ^{MPC} , 10/04/2016 ^{MPC} , 08/01/2017 ^{MPC} , 06/05/2018 ^{MPC} , 06/04/2019 ^{MPC} , 06/02/2020 ^{MPC} , 06/01/2021 ^{MPC} , 06/07/2022 ^{MPC} , 06/06/2023 ^{MPC} , 03/12/2024 ^{MPC}	09/05/2023

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
06/26/2020	Added "Kaiser Permanente Medical Policy" statement under Medicare section
02/06/2023	Added CPT code 31627 to criteria page
09/05/2023	MPC approved to adopt Endobronchial Ultrasound, MCG A-1049 for clinical coverage indications. Requires 60-day notice; effective February 1, 2024.
02/22/2024	Updated formatting for clarity.