

Comment and Response Document

LCD Database ID Number

L30510

LCD Title

Electromagnetic Navigation Bronchoscopy (ENB)

Contractor's Determination Number

PULM-007

Comment: The indications and essential components of ENB narrowly defines only one device that uses Electromagnetic Navigation Bronchoscopy (ENB) to facilitate the biopsy of identified tissue. We are requesting language that provides a more general description of ENB to allow coverage of similar devices that use ENB to facilitate the biopsy of similarly identified tissue. Rather than describe each unique, slight variation of each device, we propose a general description of the essential elements to encompass the generally similar configurations of using ENB to biopsy identified tissue. The recommended changes include new language for the second paragraph under Indications and Description of the Essential Elements of ENB. Suggested language changes:

The ENB system consists of four essential components recommended language:

1. Computer software that creates a three-dimensional (3D) virtual bronchoscopy reconstruction from CT images;
2. An electromagnetic location generator with the means to emit a low-dose electromagnetic field;
3. A steerable sensor probe that is locatable within the electromagnetic field, and
4. A working channel (EWC) that enables the placement of the bronchoscopic tools to the lung periphery.

A registration process utilizing either point registration or can be obtained with other techniques to capture specific landmarks that are non-anatomical (fiducials) or using pathway registration techniques

Response:

We agree the components were narrowly defined and have incorporated a few of your suggestions. The 4 components of ENB have been changed to:

The ENB system consists of four essential components:

1. Computer software that creates a three-dimensional (3D), virtual bronchoscopy reconstruction from CT images;
2. An electromagnetic location board which emits a low-dose electromagnetic field;
3. A steerable sensor probe that is locatable within the electromagnetic field, and
4. An extended working channel (EWC) that when secured enables the placement of the bronchoscopic tools to the lung periphery.

We did not think the sentence on the registration process added to the LCD and was not included in the policy.

Comment:

How does this procedure change the treatment of the patient? If a physician suspects a peripheral nodule is malignant the nodule is surgically removed and then biopsied. That is and has been the gold standard.

Response:

This procedure offers an option for those patients that may not be able to tolerate a more invasive procedure. This procedure is limited to lesions that are poorly accessible by standard bronchoscopy.