Medical Coverage Policy | Electromagnetic Navigation Bronchoscopy

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 07|07|2015

OVERVIEW
Electromagnetic navigation bronchoscopy (ENB) is intended to enhance standard bronchoscopy by providing a 3-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. The purpose of ENB is to allow navigation to distal regions of the lungs, so that suspicious lesions can undergo biopsy and to allow for placement of fiducial markers.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Electromagnetic navigation bronchoscopy is considered not medically necessary for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes.

Electromagnetic navigation bronchoscopy is considered not medically necessary for the placement of fiducial markers.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
ENB uses computed tomography (CT) scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, data are insufficient to determine the risks and benefits of ENB compared with standard approaches to diagnose peripheral lesions.

Pulmonary nodules are identified on plain chest radiographs or chest CT scans. Although most of these nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when it is diagnosed later in the disease course. The method used to diagnose lung cancer depends on a number of factors, including lesion size and location, as well as the clinical history and status of the patient. There is generally greater diagnostic success with centrally located and larger lesions.

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 diagnosing them; none of the methods are ideal for safely and accurately diagnosing malignant disease.

Recent advances in technology have led to enhancements that may increase the yield of established diagnostic methods. CT scanning equipment can be used to guide bronchoscopy and bronchoscopic transbronchial needle biopsy but have the disadvantage of exposing the patient and staff to radiation. Endobronchial ultrasound (EBUS) by radial probes, previously used in the perioperative staging of lung cancer, can also be

used to locate and guide sampling of peripheral lesions. EBUS is reported to increase the diagnostic yield of flexible bronchoscopy to at least 82%, regardless of the size and location of the lesion.

Another proposed enhancement to standard bronchoscopy is ENB. This technology uses CT scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. The InReach™ system was the first ENB system cleared for marketing by FDA. The 3 phases of the procedure using the InReach system are as follows:

1. **Planning phase:** Proprietary software is used to take previously taken CT scans and construct a 3-dimensional image of the patient's lungs, with anatomical landmarks identified. The file containing this information is transferred to a computer on the InReach computer console for use during the procedure;
2. **Registration phase:** A steerable navigation catheter is placed through the working channel of a standard bronchoscope. The anatomical landmarks identified in the planning phase are viewed on the 3-dimensional image from phase 1, and these virtual images are correlated with the actual image from the video bronchoscope. The steerable navigation catheter is placed at the same site as the virtual markers, and the position of each is marked using a foot petal;
3. **Navigation phase:** The steerable navigation catheter is moved toward the target, and the real-time location of the catheter's tip is displayed on the CT images. When the navigation catheter reaches the target, it is locked in place and the working guide is retracted.

Once the navigation catheter is in place, any endoscopic tool can be inserted through the channel in the catheter to the target. This includes insertion of transbronchial forceps to biopsy the lesion. In addition, the guide catheter can be used to place fiducial markers. Markers are loaded in the proximal end of the catheter with a guide wire inserted through the catheter.

Electromagnetic navigation bronchoscopy uses computed tomography scans to improve the ability of standard bronchoscopic procedures to reach lesions in the periphery of the lungs. Overall, data are insufficient to determine the risks and benefits of ENB compared with standard approaches to diagnose peripheral lesions. The data are also insufficient to identify which patients might benefit from ENB. Thus, use of this technology is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary:

31626
31627

RELATED POLICIES

Not applicable

PUBLISHED

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