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Subject: Computer Assisted Surgical Navigation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions | Related Guidelines | Other | References | Update

DESCRIPTION:

NOTE: This Medical Coverage Guideline addresses computer assisted surgical navigational procedures that do not have a specific Medical Coverage Guideline.

Computer assisted surgical navigation combines imaging with navigational computer software for displaying images, localizing surgical targets, facilitating view of non-visualized anatomy and aiding physicians in guiding endoscopic tools. Computer assisted surgical navigation use computer technology, which facilitate pre-surgical planning and for guiding and performing surgical procedures.

Computer assisted surgical navigational may be performed in addition to a primary procedure (e.g., biopsy, endoscopy, surgery). The U.S. Food and Drug Administration (FDA) have cleared through the 510(k) process several devices (e.g., superDimension/Bronchus, LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software, ig4™ System) for displaying images, placement of markers and for guiding endoscopic tools or catheters in the pulmonary tract.

Electromagnetic navigation bronchoscopy (ENB) combines simultaneous computed tomography (CT) virtual bronchoscopy with real-time fiberoptic bronchoscopy. ENB is intended to enhance standard bronchoscopy by providing a three-dimensional roadmap of the lungs and real-time information about the position of the steerable probe during bronchoscopy. Electromagnetic navigation bronchoscopy during flexible bronchoscopy has been proposed as a method to further increase the diagnostic yield of bronchoscopy in the diagnosis of peripheral and mediastinal lung lesions and insertion of endoscopic tools (needle, brush, forceps) for lesion sampling, fiducial and dye marker placement prior to treatment.

For Computer assisted surgical navigational procedure for orthopedic procedures, refer to MCG 02-20000-30, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure Medical Coverage Guideline.

Summary and Analysis of Evidence: Muñoz-Largacha et al (2017) evaluated the effectiveness of electromagnetic navigational bronchoscopy (ENB) with dye marking to aid minimally invasive resection. Patients with peripheral pulmonary nodules underwent ENB before planned thoracoscopic or robotic-assisted thoracoscopic resection. Methylene blue was injected directly into the lesion for pleural-based lesions or peripherally for lesions deep to the pleural surface. Surgical resection was then immediately performed. Technical success was defined as identification of the dye marking within/close to the lesion with pathological confirmation after minimally invasive surgical resection. Seventeen patients (19 nodules) underwent ENB with dye marking followed by minimally invasive resection. Median lesion size was 9 mm

(4-32 mm) and the median distance from the pleura was 9.5 mm (1-40 mm). Overall success rate was 79% (15/19). In two cases the dye was not visualized and in the remaining two there was extravasation of dye into the pleural space. There were trends favoring technical success for nodules that were larger or closer to the pleural surface. Five patients required adhesiolysis to visualize the target lesion and all were successful. There were no significant adverse events, and a definitive diagnosis was ultimately accomplished in all patients. ENB with dye marking is useful for guiding minimally invasive resection of small peripheral lung nodules. ENB can be undertaken immediately before performing resection in the operating room. This improves workflow and avoids the need for a separate localization procedure. Several clinical studies suggests that ENB is an effective and safe procedure in diagnosing peripheral lung lesions (Ozgul et al 2016, Muñoz-Largacha et al 2017, McGuire et al 2020, Folch et al 2020)

POSITION STATEMENT:

Electromagnetic navigation bronchoscopy **meets the definition of medical necessity** for any of the following:

- Member with a suspicious solitary pulmonary nodule that is inaccessible by standard bronchoscopy or endobronchial ultrasound (EBUS) and there is a low probability of diagnostic yield; **OR**
- Member with a suspicious solitary pulmonary nodule where an invasive procedure (e.g., percutaneous lung biopsy) pose a risk to the member because of conditions (e.g., bullous lung disease, diffuse emphysema); **OR**
- Member with an identified lung lesion(s) and a co-existing cancer in whom further determination of the lung lesion(s) will impact staging and treatment of the primary tumor; **OR**
- Placement of fiducial markers in member who is not a candidate for surgical intervention and who have elected to undergo radiation therapy.

Electromagnetic navigation bronchoscopy is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Exclusions:

Electromagnetic navigation for bronchoscopy **does not meet the definition of medical necessity** when any of the following conditions exist:

- The member has a solitary pulmonary nodule that is stable on imaging tests for at least two years.
- The member has a solitary pulmonary nodule that is calcified in a clearly benign pattern.
- The member has a low pretest probability of malignancy (<30 to 40%) and an indeterminant solitary pulmonary nodule that measures at least 8 to 10 mm in diameter, and the lesion is not hypermetabolic by FDG-PET imaging, or does not enhance .15 HU on dynamic contrast CT.
- CT scan indicates the lesion is accessible by a standard flexible bronchoscopy.

Computer assisted surgical navigational, refer to **REIMBURSEMENT INFORMATION**.

BILLING/CODING INFORMATION:

CPT Coding:

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[s])

REIMBURSEMENT INFORMATION:

The use of device(s) (e.g., surgical, software, other [specified and unspecified]) in conjunction with or without computer assisted surgical navigational procedures is considered an integral part of the primary surgical procedure and is not separately reimbursable.

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for electromagnetic navigation bronchoscopy.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Radiology reason for study	18785-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Radiology comparison study-date and time	18779-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Radiology comparison study observation	18834-2	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Radiology-study observation	18782-3	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure, 02-20000-30

OTHER:

Other names used to report computer assisted surgical navigational procedures:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Computer aided surgery
Computer assisted intervention
Computer assisted surgery
Electromagnetic navigation (EMN)
Electromagnetic navigation bronchoscopy (ENB)
Image guided surgery
Surgical navigation

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/27/26.

GUIDELINE UPDATE INFORMATION:

03/15/09	New Medical Coverage Guideline.
01/01/10	Annual HCPCS coding update: added 31627, and updated references.
03/15/10	Scheduled review. No change in position statement (experimental or investigational), and updated references.
01/01/11	Annual HCPCS coding update: added 61781, 61782 and 61783.
01/15/11	Deleted codes 61781, 61782 and 61783.
03/15/11	Annual review: position statements maintained, updated description; added FDA information regarding superDimension/Bronchus System and LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software, added “and placement of fiducial markers” to position statement, revised reimbursement information; added software and wording “or without”, added Medicare Advantage program exception, and updated references.
02/15/13	Updated Medicare Advantage products program exception.
05/11/14	Revision: Program Exceptions section updated.
09/15/16	Review; no change to position statement. Removed “procedures and devices” from subject. Updated references.
10/15/17	Review; no change in position statement. Updated references.
09/15/18	Review; position statement added for solitary pulmonary nodule, lung lesion and fiducial markers. Revised computer assisted surgical navigation position statement. Updated references.
08/15/19	Review; no change in position statement. Updated references.
08/15/21	Review; revised computer assisted surgical navigational statement. Updated references.
09/15/23	Review; no change in position statement. Updated references.
09/15/24	Review; no change in position statement. Updated references.
09/15/25	Review; no change in position statement. Updated references.
09/15/26	Review; no change in position statement.