02-99221-14

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Reviewed: 08/24/23

Revised: 09/15/23

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	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Update</u>			

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 <u>02-20000-30</u>, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure Medical Coverage Guideline.

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 vield; 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. There is insufficient clinical evidence published in the peer-reviewed literature on the effects of electromagnetic navigation bronchoscopy on health outcomes.

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 physician progress notes, plan of treatment and reason for electromagnetic navigation bronchoscopy.

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

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

REFERENCES:

- 1. Al-Jaghbeer M, Marcus M, Durkin M et al. Diagnostic yield of electromagnetic navigational bronchoscopy. Therapeutic Advances in Respiratory 2016 Aug; 10 (4):295-299.
- 2. Al-Zubaidi N, Soubani AO. Advances in diagnostic interventional pulmonary. Avicenna Journal Medicine 2015; 5(3): 57-66.
- 3. Anatham D, Feller-Kopman D, Shanmugham LN et al. Electromagnetic navigation bronchoscopyguided fiducial placement for robotic stereotactic radiosurgery of lung tumors. Chest 2007; 132:930-935.
- 4. Asano F, Matsuno Y, Shinagawa N et al. A virtual bronchoscopic navigation system for pulmonary peripheral lesions. Chest 2006; 130:559-566.

- 5. Awais O, Reidy MR, Mehta et al. Electromagnetic Navigation Bronchoscopy-Guided Dye Marking for Thoracoscopic Resection of Pulmonary Nodules. Annals of Thoracic Surgery 2016 Jul; 102(1):223-229.
- 6. Baumhauer M, Feuerstein M, Meinzet HP et al. Navigation in endoscopic soft tissue surgery: perspectives and limitations. Journal of Endourology 2008; 22(4): 751-66.
- 7. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.122 Electromagnetic Navigational Bronchoscopy, 07/23.
- 8. Bolton WD, Howe H 3rd, Stephenson JE. The utility of electromagnetic navigational bronchoscopy as a localization tool for robotic resection of small pulmonary nodules. Annals of Thoracic Surgery 2014 Aug; 98(2):471-475.Bowling MR, Folch EE, Khandhar S et al. Fiducial marker placement with electromagnetic navigation bronchoscopy: a subgroup analysis of the prospective, multicenter NAVIGATE study. Ther Adv Respir Dis 2019 Apr;13:1753466619841234.
- 9. Dale CR, Madtes DK, Fan VS. Navigational bronchoscopy with biopsy versus CT-guided biopsy for the diagnosis of a solitary pulmonary nodule: a cost-consequences analysis. Journal Bronchology Intervention Pulmonology 2013; 19(4): 294-303.
- Detterbeck FC, Lewis SZ, Diekemper R et al. Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest 2013; 143(5): 7S-37S.
- 11. Du Rand IA, Barber PV, Goldring J, et al. British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax 2011; 66(Suppl 3): iii1-21.
- 12. Eberhardt R, Anantham D, Herth F et al. Electromagnetic navigation diagnostic bronchoscopy in peripheral lung lesions. Chest 2007; 131: 1800-1805.
- 13. Eberhardt R, Anantham D, Ernst A et al. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. American Journal of Respiratory and Critical Care Medicine 2007; 176: 37-41.
- 14. Eberhardt R, Kahn N, Gompelmann D et al. LungPoint--a new approach to peripheral lesions. Journal of Thoracic Oncology 2010 Oct; 5(10):1559-1563.
- 15. Eberhardt R, Morgan RK, Ernst A et al. Comparison of suction catheter versus forceps biopsy for sampling of solitary pulmonary nodules guided by electromagnetic navigational bronchoscopy. Respiration. 2010;79(1):54-60.
- 16. Fengqiang L, Jiadong Q, Yi L. Computer-assisted stereotactic neurosurgery with framework neurosurgery. Clinical Neurology and Neurosurgery 2008: 110(7): 696-700.
- 17. Folch EE, Bowling MR, Gildea TR et al. Design of a prospective, multicenter, global, cohort study of electromagnetic navigation bronchoscopy. BMC Pulmonary Medicine 2016 Apr 26; 16(1):60.
- 18. Folch, EE, Pritchett, MM, Nead, MM et al. Electromagnetic navigation Bronchoscopy for peripheral pulmonary lesions: one-year results of the prospective, multicenter NAVIGATE study.. J Thorac Oncol 2018 Nov 27;14(3).
- 19. Gex G, Pralong JA, Combescure C et al. Diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules: a systematic review and meta-analysis. Respiration. 2014;87(2):165-176.
- 20. Gildea TR, Mazzone PJ, Karnak D et al Electromagnetic navigation diagnostic bronchoscopy: a prospective study. American Journal of Respiratory and Critical Care Medicine 2006; 176: 982-989.
- 21. Gould MK, Donington J, Lynch WR et al. Evaluation of individuals with pulmonary nodules: When is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2013; 143(5 Suppl.): e93S-e120S.

- 22. inReach-superDimension inResearch™ System, 2008.
- 23. Kalfas IH. Image-guided spinal navigation: application to spinal metastases. Neurosurgical Focus 2001; 11(6): 1-10.
- 24. Khan KA, Nardelli P, Jaeger A et al. Navigational Bronchoscopy for Early Lung Cancer: A Road to Therapy. Advances in Therapy 2016 Apr; 33(4):580-596.
- 25. Khandhar SJ, Bowling MR, Flandes J. Electromagnetic navigation bronchoscopy to access lung lesions in 1,000 subjects: first results of the prospective, multicenter NAVIGATE study. BMC Pulmonary Medicine 2017; 17(1):59.
- 26. Krimsky WS, Minnich DJ, Cattaneo SM et al. Thoracoscopic detection of occult indeterminate pulmonary nodules using bronchoscopic pleural dye marking. Journal of Community Hospital Internal Medicine Perspectives 2014 Feb 17;4.
- 27. Lamprecht B, Porsch P, Wegleitner B et al. Electromagnetic navigation bronchoscopy (ENB): Increasing diagnostic yield. Respiratory Medicine 2012; 106(5): 710-715.
- 28. Leong S, Ju H, Marshall H et al. Electromagnetic navigation bronchoscopy: A descriptive analysis. Journal of Thoracic Disease 2012; 1(4): 173-185.
- 29. Loo FL, Halligan AM, Port JL et al. The emerging technique of electromagnetic navigation bronchoscopy-guided fine-needle aspiration of peripheral lung lesions: promising results in 50 lesions. Cancer Cytopathology 2014; 122(3): 191-199.
- 30. Makris D, Scherpereel A, Leroy S et al. Electromagnetic navigation diagnostic bronchoscopy for small peripheral lung lesions. European Respiratory Journal 2007; 29(6): 1187-1192.
- 31. Marino KA, Sullivan JL, Weksler B. Electromagnetic Navigation Bronchoscopy for Identifying Lung Nodules for Thoracoscopic Resection. Annals of Thoracic Surgery 2016 Aug; 102(2):454-457.
- 32. Mezger U, Jendrewaki C, Barteis M. Navigation in surgery. Longenbeck's Archives of Surgery 2013; 398:501-514.
- 33. Muñoz-Largacha JA, Ebright MI, Litle VR et al. Electromagnetic navigational bronchoscopy with dye marking for identification of small peripheral lung nodules during minimally invasive surgical resection. Journal of Thoracic Disease 2017 Mar; 9(3):802-808.
- 34. Muñoz-Largacha JA, Litle VR, Fernando HC. Navigation bronchoscopy for diagnosis and small nodule location. Journal of Thoracic Disease 2017 Mar; 9(Suppl 2):S98-S103.
- 35. Rivera MP, Mehta AC, Wahidi MM. Establishing the Diagnosis of Lung Cancer, Diagnosis and Management of Lung Cancer,3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2013; 143 (5)(Suppl): e143S-e165S.
- 36. National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines)® Lung Cancer Screening Version 1.2019-June 11, 2018.
- 37. National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines)® Non-Small Cell Lung Cancer Version 5.2018-June 27, 2018.
- 38. Ost DE, Ernst A, Lei X et al. Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions. Results of the AQuIRE Registry. American Journal of Respiratory and Critical Care Medicine 2016 Jan 1;193(1):68-77.
- 39. Ozgul G, Cetinkaya E, Ozgul MA. Efficacy and safety of electromagnetic navigation bronchoscopy with or without radial endobronchial ultrasound for peripheral lung lesions. Endoscopic Ultrasound 2016; 5(3): 189-95.
- 40. Port J, Harrison S. Electromagnetic navigational bronchoscopy. Seminars in Interventional Radiology 2013; 30(2): 128-132.

- 41. Rivera MP, Mehta AC, Wahidi MM. Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed.: American College of Chest Physicians evidence-based clinical practice guidelines. Chest 2013; 143(5Suppl): e142S-e165S.
- 42. Rivera MP, Mehta AC; American College of Chest Physicians. Initial diagnosis of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007; 132(3 Suppl): 131S-148S.
- 43. Santos RS, Gupta A, Ebright MI, DeSimone M et al. Electromagnetic navigation to aid radiofrequency ablation and biopsy of lung tumors. Annals of Thoracic Surgery 2010 Jan; 89(1):265-268.
- 44. Schulz C, Waldeck S, Mauer UM. Intraoperative image guidance in neurosurgery: development, current indications, and future trends. 2012. Radiology Research and Practice 2012; 2012:197364.
- 45. Schramm A, Suarez-Cunqueiro MM, Barth EL et al. Computer-assisted navigation in carniomaxillofacial tumors. Journal of Carniofacial Surgery 2008:19(4): 1067-1074.
- 46. Schwartz Y, Greif J, Becker H et al. Real-time electromagnetic navigation bronchoscopy to peripheral lung lesions using overlaid CT images: the first human study. Chest 2006; 129; 988-994.
- 47. Staecker H, O'Malley BW, Eisenberg H et al. Use of the LandmarX™ surgical navigational system in lateral skull base and temporal bone surgery. Skull Base 2001; 11(4): 245-255.
- 48. Sun X, Su Y, Li S, et al. [Diagnostic Value and Safety of Electromagnetic Navigation Bronchoscopy in Peripheral Pulmonary Lesions: a Meta-Analysis). Zhongguo Fei Ai Za Zhi. 2023 Feb 20;26(2):119-134. [Abstract]
- 49. U.S. Food and Drug Administration (FDA) 510(k) K091934 Premarket Notification Database-ig4™ Endobronchial, 12/02/09.
- 50. U.S. Food and Drug Administration (FDA) 510(k) K042438 Premarket Notification Database-Superdimension/Bronchus, 11/08/04.
- 51. U.S. Food and Drug Administration (FDA) 510(k) K091160 Premarket Notification Database-LungPoint™Virtual Bronchoscopic Navigation (VBN) Software, 05/05/09.
- 52. Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. Chest 2012; 142(2): 385-393.
- 53. Weiser TS, Hyman K, Yun J et al. Electromagnetic navigational bronchoscopy: a surgeon's perspective. The Annals of Thoracic Surgery 2008; 85(2): S797-S801.
- 54. Wiener RS, Schwartz LM, Woloshin S et al. Population-based risk for complications after transthoracic needle lung biopsy of a pulmonary nodule: an analysis of discharge records. Population-based risk of complications following transthoracic needle lung biopsy of a pulmonary nodule Annals of Internal Medicine 2011; 155(3): 137-144.
- 55. Zhang W, Chen S, Dong X et al. Meta-analysis of the diagnostic yield and safety of electromagnetic navigation bronchoscopy for lung nodules. Journal of Thoracic Disease 2015; 7(5): 799-809.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/24/23.

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.			