



Electromagnetic Navigation Bronchoscopy

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Electromagnetic navigation 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.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
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National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	<i>Medicare coverage guidance is not available for electromagnetic navigation bronchoscopy. Therefore, the health plan's medical policy is applicable.</i>

Electromagnetic Navigation Bronchoscopy, [Surgery, Policy No. 179](#) (see “NOTE” below)”

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

In September 2004, the superDimension/Bronchus™ InReach™ system was cleared for marketing by the United States Food and Drug Administration (FDA) through the 510(k) process. The system includes planning and navigation software, a disposable extended working channel, and a disposable steerable guide. The FDA determined that this device was substantially equivalent to existing bronchoscopic devices. It is indicated for displaying images of the tracheobronchial tree that aids physicians in guiding endoscopic tools in the pulmonary tract. The device is not intended as an endoscopic tool; it does not make a diagnosis; and it is not approved for pediatric use. In May 2012, superDimension was acquired by Covidien. The current version of the product is called i-Logic™ Electromagnetic Navigation Bronchoscopy.

In December 2009, the ig4™ EndoBronchial system was cleared for marketing by FDA through the 510(k) process. The system was considered to be substantially equivalent to the InReach™ and is marketed as the SPiN™ Drive system.

Several additional navigation software-only systems have been cleared for marketing by FDA through the 510(k) process. These include:

- December 2008: The LungPoint® virtual bronchoscopic navigation (VPN) system.

- June 2010: The bf-NAVI virtual bronchoscopic navigation (VPN) system.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

[Whole Body CT Screening](#), Radiology, Policy No. M-40

REFERENCES

None

CODING

Codes	Number	Description
CPT	31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance when performed; with placement of fiducial markers, single or multiple
	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)
HCPCS	A4648	Tissue marker, implantable, any type, each
	C7509	Bronchoscopy, rigid or flexible, diagnostic with cell washing(s) when performed, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
	C7510	Bronchoscopy, rigid or flexible, with bronchial alveolar lavage(s), with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
	C7511	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
	C8005	Bronchoscopy, rigid or flexible, non-thermal transbronchial ablation of lesion(s) by pulsed electric field (pef) energy, including fluoroscopic and/or ultrasound guidance, when performed, with computed tomography acquisition(s) and 3d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) of lung(s) and all mediastinal and/or hilar lymph node stations or structures, and therapeutic intervention(s)
	C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with

computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.