Electromagnetic Navigation Bronchoscopy

Policy # 00247
Original Effective Date: 01/20/2010
Current Effective Date: 04/19/2017

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Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes to be investigational.*

Based on review of available data, the Company considers electromagnetic navigation bronchoscopy (ENB) for the placement of fiducial markers to be investigational.*

Background/Overview
Electromagnetic navigation bronchoscopy 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. The purpose of ENB is to allow navigation to distal regions of the lungs, so that suspicious lesions can be biopsied and to allow for placement of fiducial markers.

Pulmonary nodules are identified on plain chest radiographs or chest computed tomography (CT) scans. (Note that screening for lung cancer and whole-body CT tests for screening are considered investigational). Although most of these nodules are benign, some are cancerous, and early diagnosis of lung cancer is desirable because of the poor prognosis when cancer 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.

Peripheral lung lesions and solitary pulmonary nodules (SPN, 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 is ideal for safely and accurately diagnosing malignant disease. Sputum cytology is the least invasive approach. Reported sensitivity rates are relatively low and vary widely across studies; sensitivity is lower for peripheral lesions. Sputum cytology, however, has a high specificity; and a positive test may obviate the need for more invasive testing. Flexible bronchoscopy, a minimally invasive procedure, is an established approach to evaluate pulmonary nodules. The sensitivity of flexible bronchoscopy for diagnosing bronchogenic carcinoma has been estimated at 88% for central lesions and 78% for peripheral lesions. For small peripheral lesions (<1.5 cm in diameter), the sensitivity may be as low as 10%. The diagnostic accuracy of transthoracic needle aspiration for solitary pulmonary nodules tends to be higher than that of bronchoscopy; the sensitivity and specificity are both approximately 94%. A disadvantage of transthoracic needle aspiration is that a pneumothorax develops in 11% to 24% of patients, and 5% to 14% require insertion of a chest tube. Positron emission tomography scans are also highly sensitive for evaluating pulmonary nodules, yet may miss lesions less than 1 cm in size. Lung biopsy is the criterion standard for diagnosing pulmonary nodules but is an invasive procedure.
Recent advances in technology have led to enhancements that may increase the yield of established diagnostic methods. Computed tomography 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. Endobronchial ultrasound 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. 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. 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.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration
In September 2004, the superDimension/Bronchus™ InReach™ system (superDimension Ltd, Herzliya, Israel) was cleared for marketing by the 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-cleared indication is 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. As of June 2016, the current version of the product is the Medtronic SuperDimension Navigation System (Medtronic, Minneapolis, MN).

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

Several additional navigation software-only systems have been cleared for marketing by the FDA through the 510(k) process. These include:
- December 2008: The LungPoint® virtual bronchoscopic navigation (VPN) system (Broncus Technologies, Mountain View, CA).
- June 2010: The bf-NAVI VPN system (Emergo Group, Austin, TX)

FDA product codes: JAK and LLZ.

Centers for Medicare and Medicaid Services (CMS)
No national coverage determination.

**Rationale/Source**
This policy is updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through April 25, 2016. The key literature is summarized below.
Electromagnetic Navigation Bronchoscopy for the Diagnosis of Pulmonary Lesions

Evaluation of EBN as a diagnostic tool involves examining the:

1. Navigation accuracy and biopsy success rate: The frequency with which the steerable navigation catheter is able to reach a peripheral nodule previously identified on CT scans, and, once reached, the frequency with which biopsies are successfully obtained.

2. Diagnostic accuracy compared to other methods: The ideal study design would include a gold standard (e.g., surgical biopsy and/or long-term follow-up) on all samples. Of particular interest is the negative predictive value (NPV), the proportion of patients with negative test results who are correctly diagnosed. If the NPV is high, we can have confidence that patients who test negative do not need additional interventions.

3. Complication rates compared to other methods of diagnosis.

Systematic Reviews

A systematic review of the literature was published in 2015 by Zhang et al. The authors updated a 2014 systematic review by Gex et al, with the addition of newer studies. The Zhang review included prospective and retrospective studies of patients with peripheral nodules confirmed by radiographic evaluation that had more than 10 patients and reported the diagnostic yield of ENB for peripheral lung nodules or lesions. A total of 17 studies with 1161 lung nodules or lesions in 1106 patients met the eligibility criteria. The authors used the Quality Assessment of Diagnostic Accuracy Studies tool to evaluate the methodologic quality of selected studies, and overall quality was poor. None compared ENB with surgery, and, in almost all studies, the authors reported it was uncertain whether the selected patients were representative of the population that would undergo ENB in an actual clinical setting.

Results of pooled analyses are reported in Table 1. True positive findings are those in which ENB biopsy yielded a definitive malignant diagnosis. True negatives were defined as benign findings on ENB biopsy, confirmed by follow-up procedures.

### Table 1. Meta-Analysis of Electromagnetic Navigation Bronchoscopy Performance Reported by Zhang et al (2015)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Rate (95% Confidence Interval), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity for malignancy</td>
<td>82 (79 to 85)</td>
</tr>
<tr>
<td>Specificity for malignancy</td>
<td>100 (98 to 100)</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>18.67 (9.04 to 38.55)</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>0.22 (0.15 to 0.32)</td>
</tr>
<tr>
<td>Diagnostic odds ratio</td>
<td>97.36 (43.75 to 216.69)</td>
</tr>
</tbody>
</table>

The Gex systematic review, which included 15 studies (total N=971 patients) reported somewhat different outcomes (see Table 2).

### Table 2. Meta-Analysis of Electromagnetic Navigation Bronchoscopy Performance Reported by Gex et al (2014)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Rate (95% Confidence Interval), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navigation success</td>
<td>97.4 (95.4 to 98.5)</td>
</tr>
<tr>
<td>Diagnostic yield</td>
<td>64.9 (59.2 to 70.3)</td>
</tr>
</tbody>
</table>
Sensitivity for malignancy: 71.1 (64.6 to 76.8)
Accuracy for malignancy: 78.6 (72.8 to 83.4)
Negative predictive value: 52.1 (43.5 to 60.6)
Negative predictive value of intermediate benign results: 78.5 (53.1 to 92.1)

As reported by Gex, whereas the navigation success rate using ENB was generally very high, the diagnostic yield and negative predictive value were relatively low. Moreover, in Zhang, the positive likelihood ratio was large but the negative likelihood ratio (0.22) suggested only a small decrease in the likelihood of disease following the test. (Zhang did not conduct a pooled analysis of diagnostic yield.) As stated at the beginning of this section, we are particularly interested in evidence that the test can correctly identify patients who do not have malignancy (ie, high NPV or low negative likelihood ratio). Studies included in the meta-analyses were limited because surgical biopsy was not used as the criterion standard; it is unclear whether follow-up was long enough to confirm ENB diagnoses.

The pneumothorax rate following ENB was 5.9% in Zhang and 3.1% in Gex (1.6% required chest tube placement for pneumothorax). Zhang stated that 2 of the pneumothoraces were induced by transbronchial biopsy and the others were unrelated to the ENB procedure.

Randomized Controlled Trials (RCTs)
Eberhardt and colleagues published the only RCT to evaluate ENB for the diagnosis of pulmonary nodules. This trial used surgical biopsy as a criterion standard confirmation of diagnosis. Patients were randomized to receive ENB only, EBUS only, or the combination of ENB and EBUS. Whereas ENB is designed to help navigate to the target but cannot visualize the lesion, EBUS is not able to guide navigation but enables direct visualization of the target lesion before biopsy. The trial included 120 patients who had evidence of peripheral lung lesions or SPNs and who were candidates for elective bronchoscopy or surgery. In all 3 arms, only forceps biopsy specimens were taken, and fluoroscopy was not used to guide the biopsies. The primary outcome was diagnostic yield, defined as the ability to yield a definitive diagnosis consistent with clinical presentation. If transbronchial lung biopsy was not able to provide a diagnosis, patients were referred for surgical biopsy. The mean (SD) size of the lesions was 26 (6) mm.

Two patients who did not receive a surgical biopsy were excluded from the final analysis. Of the remaining 118 patients, 85 (72%) had a diagnostic result via bronchoscopy and 33 required a surgical biopsy. The diagnostic yield by intervention group was 59% (23/39) with ENB only, 69% (27/39) with EBUS only, and 88% (35/40) with combined ENB/EBUS; the yield was significantly higher in the combined group. The NPV for malignant disease was 44% (10/23) with ENB only, 44% (7/16) with EBUS only, and 75% (9/12) with combined ENB/EBUS. Note that the number of cases was small, and thus the NPV is an imprecise estimate. Moreover, the authors stated in the discussion that the yield in the ENB-only group is somewhat lower than in other studies and attribute this to factors such as the use of forceps for biopsy (rather than forceps and endobronchial brushes) and/or an improved diagnosis using a gold standard. The pneumothorax rate was 6%, which did not differ significantly among the 3 groups.
Uncontrolled Studies

Key uncontrolled studies not included in the meta-analyses are described next. In 2016, Ost et al published data from the AQuire Registry, a study of consecutive patients from multiple centers who underwent transbronchial biopsy for evaluation of peripheral lung lesions. The primary outcome of this analysis was the diagnostic yield of bronchoscopy, defined as the ability to obtain a specific malignant or benign diagnosis. Bronchoscopy was diagnostic in 312 (53.7%) of 581 peripheral lesions. Diagnostic yield was 63.7% for bronchoscopy with no EBUS or ENB, 57.0% with EBUS alone, 38.5% with ENB alone, and 47.1% with ENB plus EBUS. Complications occurred in 13 (2.2%) of 591 patients. Pneumothorax occurred in 10 (1.7%) patients, 6 of whom required chest tubes. Pneumothorax rates were not reported for bronchoscopy with and without ENB.

Two prospective observational studies have examined the sequential use of ENB: EBUS was used initially, with the addition of ENB when EBUS failed to reach or diagnose the lesion. A 2013 study by Chee et al included 60 patients with peripheral pulmonary lesions. Patients either had a previous negative CT-guided biopsy or did not have one due to technical difficulties. An attempt was first made to identify the lesion using peripheral EBUS and, if not identified, then an ENB system was used. Nodules were identified by EBUS alone in 45 (75%) of 60 cases. ENB was used in 15 (25%) cases, and in 11 (73%) of these cases the lesion was identified. Peripheral EBUS led to a diagnosis in 26 cases and ENB in an additional 4 cases, for a total diagnostic yield of 30 (50%) of 60 cases. In this study, the extent of improved diagnosis with ENB over EBUS alone was not statistically significant (p=0.125). The rate of pneumothorax was 8% (5/60 patients); the addition of ENB did not alter the pneumothorax rate.

In 2016, Steinfort et al published findings on 236 patients with 245 peripheral pulmonary lesions who underwent bronchoscopic investigation. EBUS and virtual bronchoscopy (VB) were used initially, and ENB was performed when EBUS could not locate the lesion or when rapid onsite cytologic evaluation (ROSE) could not be successfully performed. A total of 188 (77%) of 245 lesions were localized with EBUS and VB. ENB was used in the remaining 57 cases and lesion localization was achieved in an additional 17 cases (29.8% of those undergoing ENB). The addition of ENB increased the localization rate from 77% to 85.3%.

ROSE was diagnostic for 138 (71%) of the 188 lesions that were reached with EBUS and VB. Thus, the diagnostic yield of EBUS plus VB was 134 (54.7%) of 245 lesions. An additional 9 (15.8%) of 57 ENB procedures were diagnostic, improving the overall diagnostic yield from 54.7% to 58.4%. However, the authors noted that in only 4 of the 9 procedures was the diagnostic outcome clearly attributable to accurate localization of the image with ENB. The authors did not conduct statistical analyses of diagnostic yield with EBUS versus EBUS with ENB.

Section Summary: Electromagnetic Navigation Bronchoscopy for the Diagnosis of Pulmonary Lesions

The evidence on ENB for diagnosis of pulmonary lesions includes meta-analyses, 1 RCT, and a number of observational studies. The most recent meta-analysis, which included 17 studies, reported a large pooled positive likelihood ratio but a small negative likelihood ratio. Similarly, a 2014 meta-analysis with 15 studies found that navigation success was high, but diagnostic yield and NPV were relatively low. Both meta-analyses judged the quality of published studies to be low. The single RCT found higher diagnostic yield.
when both ENB and EBUS were used compared with either intervention alone, but did not include a group without either ENB or EBUS. Two uncontrolled studies of sequential use of ENB after failure of EBUS to locate lesions or result in a diagnosis found a moderate increase in diagnostic yield when ENB was used.

Most of the published studies had small sample sizes and thus there is limited evidence on complications from the procedure and adverse effects such as pneumothorax. A relatively large registry study patients undergoing bronchoscopic procedures for diagnosing pulmonary lesions found a pneumothorax rate of 1.7% but did not report separately the rate with ENB.

The data are also insufficient to identify potential patient selection criteria. The meta-analyses identified lack of clear selection criteria as a key potential bias in the published literature. Overall, the evidence is insufficient to determine the added benefit of ENB compared with standard techniques for diagnosing of pulmonary lesions.

ENB for the Diagnosis of Mediastinal Lymph Nodes

Randomized Controlled Trials

One RCT was identified on ENB for the diagnosis of mediastinal lymph nodes (MLN). The trial, published in 2015 by Diken et al, included 94 patients with mediastinal lymphadenopathy with a short axis >1cm on CT and/or increased uptake on positron emission tomography. Patients were randomized to conventional transbronchial needle aspiration (TNBA; n=50) or ENB-guided TNBA (n=44). All samples were evaluated by a blinded cytopathologist. Sampling success was defined as presence of lymphoid tissue in the sample and diagnostic success was the ability to make a diagnosis using the sample. Diagnoses were confirmed by 1 of several methods such as mediastinoscopy, thorotomy, or radiologic follow-up. Final diagnoses were sarcoidosis (n=29), tuberculous lymphadenitis (n=12), non-small-cell lung cancer (n=20), small cell lung cancer (n=12), benign lymph node (n=5), and others (n=5). Sampling success was 82.7% in the ENB group and 51.6% in the conventional TNBA group (p<0.001); diagnostic success was 72.8% in the ENB group and 42.2% in the conventional TNBA group (p<0.001). When samples were stratified by MLN size, both sampling success and diagnostic success were significantly higher with ENB than conventional TNBA in MLNs 15 mm or less and more than 15 mm. The authors noted that, although EBUS-guided TBNA has been shown to have higher diagnostic yields than conventional TNBA, EBUS was not compared to ENB because it was not available at the institution in Turkey where the study was conducted. No pneumothorax or other major adverse effects were reported for either group.

Uncontrolled Studies

No large uncontrolled studies were identified that focused on ENB for the diagnosing of MLN. A 2007 series by Wilson et al included both patients with suspicious lung lesions and enlarged MLN. There was no consistent protocol for confirming diagnosis, although the authors stated that most patients were followed for confirmation of diagnosis. ENB was used to locate, register, and navigate to the lesions. Once navigation was completed, fluoroscopic guidance was used to verify its accuracy and to aid in the biopsy or TBNA. Sixty-seven (94%) of 71 MLN were successfully reached, and tissue samples for biopsy were obtained from all of these. The primary study outcome was diagnostic yield on the day of the procedure; this was obtained for 64 (96%) of 67 of the lymph nodes reached.
Section Summary: ENB for the Diagnosis of Mediastinal Lymph Nodes

There is less published literature on ENB for diagnosing MLN than for diagnosis of pulmonary lesions. One RCT identified found higher sampling and diagnostic success with ENB-guided TNBA than with conventional TNBA. EBUS, which has been shown to be superior to conventional TNBA, was not used as the comparator. The RCT did not report diagnostic accuracy of ENB for identifying malignancy, and this was also not reported in uncontrolled studies.

Electromagnetic Navigation Bronchoscopy for the Placement of Fiducial Markers

Evaluation of ENB as an aid to placement of fiducial markers involves searching for evidence that there are better clinical outcomes when ENB is used to place markers than either when fiducials are placed using another method or when no fiducial markers are used. This policy only evaluates the use of ENB to place fiducial markers; it does not evaluate the role of fiducial markers in radiation therapy.

Only 1 study was identified that compared fiducial marker placement with ENB with another method of fiducial marker placement; it was not randomized. This study, by Kupelian et al included 28 patients scheduled for radiotherapy for early-stage lung cancer. Follow-up data were available for 23 (82%) patients; 15 had markers placed transcutaneously under CT or fluoroscopic guidance, and 8 patients had markers placed transbronchially with ENB. At least 1 marker was placed successfully within or near a lung tumor in all patients. The fiducial markers did not show substantial migration during treatment with either method of marker placement. The only clinical outcome reported was rate of pneumothorax; 8 of 15 patients with transcutaneous placement developed pneumothorax, 6 of which required chest tubes. In contrast, none of the 8 patients with transbronchial placement developed pneumothorax. This study had a small sample size and a substantial dropout rate.

Several case series were identified. Sample sizes range from 9 patients to 64 patients. The 2 largest series are described next. In 2015, Bolton et al retrospectively reported on ENB fiducial marker placement in 64 patients (68 lung lesions) for guiding stereotactic radiotherapy. A total of 190 fiducial markers were placed, 133 in upper-lobe lesions and 57 markers in lower-lobe lesions. The rate of marker retention, the study's primary end point, was 156 (82%) of 190. Retention rate, by lobe, ranged from 68 (80%) of 85 in the right upper lobe to 10 (100%) of 10 in the right middle lobe. Complications included 3 (5%) unplanned hospital admissions, 2 cases of respiratory failure, and 2 cases of pneumothorax.

In 2010, Schroeder et al reported findings from a prospective study with 52 patients who underwent placement of fiducial markers using ENB. Patients all had peripheral lung tumors; 47 patients had inoperable tumors and 5 patients refused surgery. Patients were scheduled to receive tumor ablation using the stereotactic radiosurgery, which involves fiducial marker placement. The procedures were considered successful if the markers remained in place without migration during the timeframe required for radiosurgery. A total of 234 fiducial markers were deployed; 17 linear fiducial markers in 4 patients and 217 coil spring fiducial markers in 49 patients. Radiosurgery planning CT scans were performed between 7 and 14 days after fiducial marker placement. The planning CT scans showed that 215 (99%) of 217 coil spring markers and 8 (47%) of 17 linear markers remained in place, indicating a high success rate for coil spring markers. Three patients developed pneumothorax; 2 were treated with chest tubes, and 1 received observation only.
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Section Summary: ENB for the Placement of Fiducial Markers
There is only 1 study comparing ENB with another method of fiducial marker placement and only 8 patients in that study who had markers placed with ENB had data available. There are several case series, with sample sizes ranging from 9 to 64 patients, but comparative data are needed to draw conclusions about the safety and efficacy of ENB for fiducial marker placement.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Ongoing</td>
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<tr>
<td>NCT02410837a</td>
<td>NAVIGATE: Clinical Evaluation of superDimension Navigation System for Electromagnetic Navigation Bronchoscopy™‡</td>
<td>2500</td>
<td>Jul 2018</td>
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<tr>
<td>NCT01779388</td>
<td>Bronchoscopy Assisted by Electromagnetic Navigation (EMN) in the Diagnosis of Small Pulmonary Nodules</td>
<td>120</td>
<td>Dec 2019</td>
</tr>
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</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
For individuals who have suspicious pulmonary lesion(s) who receive ENB with flexible bronchoscopy, the evidence includes meta-analyses, 1 RCT, and a number of observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The most recent meta-analysis, which included 17 studies, reported a large pooled positive likelihood ratio but a small negative likelihood ratio. The single RCT found higher a diagnostic yield when both ENB and EBUS were used compared with either intervention alone, but did not include a group without ENB or EBUS. Two uncontrolled studies of sequential use of ENB following failure of EBUS to locate lesions or result in a diagnosis found a moderate increase in diagnostic yield when ENB was used. Most published studies had small sample sizes and thus there is limited evidence on complications of the procedure and adverse effects (eg, pneumothorax). The data are also insufficient to identify potential patient selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have enlarged mediastinal lymph node(s) who receive ENB with flexible bronchoscopy, the evidence includes 1 RCT and observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, and treatment-related morbidity. The RCT found higher sampling and diagnostic success with ENB-guided TNBA than conventional TNBA. EBUS, which has been shown superior to conventional TNBA, was not used as the comparator. The RCT did not report the diagnostic accuracy of ENB for identifying malignancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lung tumor(s) who need fiducial marker placement prior to treatment who receive ENB with flexible bronchoscopy, the evidence includes 1 controlled study and several uncontrolled studies. Relevant outcomes are other test performance measures, health status measures, and treatment-related
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The controlled study compared markers placed transcutaneously under computed tomography or fluoroscopic guidance or transbronchially with ENB. However, only 8 patients who had markers placed with ENB had data available. There are several case series, with sample sizes ranging from 9 to 64 patients, but comparative data are needed to draw conclusions about the safety and efficacy of ENB for fiducial marker placement. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

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Policy History
Original Effective Date: 01/20/2010
Current Effective Date: 04/19/2017
01/07/2010 Medical Policy Committee approval
01/20/2010 Medical Policy Implementation Committee approval. New policy.
10/01/2010 Coding revision only
01/06/2011 Medical Policy Committee review
01/19/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013 Medical Policy Committee review
02/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014 Medical Policy Committee review
02/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2015 Medical Policy Committee review
04/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016 Medical Policy Committee review
04/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2018

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<tr>
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| ICD-10 Diagnosis | All related diagnoses |

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B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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