Medical Policy

Subject:	Navigational Bronchoscopy		
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Description/Scope

This document addresses the use of navigational bronchoscopy (NB) devices as an aid in accessing peripheral lung lesions and masses, which may be inaccessible by standard bronchoscopy. This document includes the following techniques:

- Electromagnetic navigational bronchoscopy (ENB)
- Artificial Intelligence (AI) Tomography with Augmented Fluoroscopic Guidance
- Robotic assisted bronchoscopy

Navigational bronchoscopy has also been proposed as a means of placing fiducial markers for surgical and radiological procedures.

Position Statement

Investigational and Not Medically Necessary:

Navigational bronchoscopy is considered **investigational and not medically necessary** for all applications.

Rationale

ENB

ENB devices are used in conjunction with standard bronchoscopy and are not FDA approved as stand-alone surgical devices/procedures. ENB is used to guide the bronchoscope and bronchial tool to an intended target located in or adjacent to the bronchial tree on a path indicated by CT scan, and visualizes the target and the interior of the tree. The ENB devices include sensors placed on the chest to provide real time navigation during the procedure.

The U.S. Food and Drug Administration (FDA) has approved two devices. The SuperDimension™ Navigation System (Medtronic, Minneapolis, MN) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in 2008. The system is intended to display images of the tracheobronchial tree, aiding the physician in guiding endoscopic tools or catheters in the pulmonary tract for diagnostic purposes or to enable marker placement within soft lung tissue. The second device, SpiN Drive® System (Olympus Corporation of the America, Center Valley, PA), is also known as the ig4™ EndoBronchial System which received FDA clearance in December 2009.

Lung Biopsy

Ost and colleagues (2016) compared several methods used to obtain samples and diagnose peripheral lung nodules and masses. This retrospective study used data obtained from the American College of Chest Physicians (ACCP) Quality Improvement Registry, Evaluation, and Education (AQuIRE) program, which included 15 centers and 581

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individuals. Overall, the bronchoscopy procedures were considered diagnostic (specific diagnosis of either benign or malignancy was made) in 53.7% of the peripheral lesions (312/587). Unadjusted for other factors, the diagnostic yield of bronchoscopy alone (without radial endobronchial ultrasound [r-EBUS] or electromagnetic navigation [EMN]) was 63.7%; 57.0% with r-EBUS only; 38.5% with EMN only; and 47.1% with EMN plus r-EBUS. These lower diagnostic yields remained even after adjusting for size, location, transbronchial needle aspiration (TBNA) use or tobacco use. The authors contrast these results with those higher yield results reported in previous retrospective studies, suggesting that EMN does not perform as well outside the research setting. This study also addressed lung cancer sensitivity. The overall sensitivity for lung cancer was 60-74%. The minimum and maximum ranges were lower in those procedures which utilized EMN versus those procedures which did not (54%-69% versus 68%-79% respectively). The authors noted that there is little difference in sensitivity between best case sensitivity scenario with EMN and the worst case scenario without EMN. This may be due to limitations with this study, including the retrospective design with limited ability to use surgical resection as the diagnostic gold standard. This study does not support that EMN is superior to bronchoscopy and highlights the need for further comparator studies.

In 2017, Khandar and colleagues published the interim, 1-month results of the NAVIGATE study, a prospective, single arm, multicenter study of individuals who underwent ENB. Participants included individuals undergoing ENB procedures for lung lesion biopsy (n=964), fiducial marker placement (n=210), pleural dye marking (n=17), and/or lymph node biopsy (n=334). The majority of the lesions were in the peripheral/middle lung thirds (92.7%). The primary endpoint was index ENB-related pneumothorax rated grade ≥ 2, as it is applicable to all ENB procedures. At the 12- and 24-month follow-ups, the diagnostic yield of the index ENB procedure will be calculated as the proportion of individuals with a definitive diagnosis. One month follow-up data was obtained on 93.3% of the first 1000 primary cohort participants. Pneumothorax of grade ≥ 2 related to the ENB procedure was reported in 3.2% (32/1000) of the group. Pneumothorax of any grade was reported in 4.9% (49/1000) of the cases. There were 23 individuals who died by the 1-month follow-up, no deaths were considered to be related to the ENB device. Tissue biopsy was successful in 94.4% (910/1000) in those individuals who were diagnosed with primary lung adenocarcinoma or non-small-cell lung cancer NOS and molecular genetic testing was attempted; there was adequate tissue in 56/70 (80%). The onsite pathology sample assessments reported non-malignancy in 372/910 (40.9%) cases, malignancy in 45.8% (417/910) cases and inconclusive results in an additional 13.3% (121/910). Fiducial markers were placed in 210 individuals with operators reporting accurate placement in 208/210 (99.0%) cases. A total of eight (3.8%) grade ≥ 2 pneumothoraces were reported. The authors noted that a 1-month interim analysis is not a sufficient amount of time to calculate a true negative yield or the diagnostic yield. While the results suggest ENB might be a safe alternative for a certain population, further follow-up is needed to determine impact on long-term survival and "will help to set the benchmark for the ideal ENB patient, and define the procedural techniques contributing to enhanced performance" (Khandhar, 2017).

In 2019, the 1-year results of the NAVIGATE study were reported by Folch and colleagues. The purpose of 12-month follow-up was to determine the true diagnosis (malignant or nonmalignant). The study defined initial negative results as results that were diagnostic of a nonmalignant condition or indeterminate results. At 12 months post-procedure, cases reporting subsequent diagnostic tests confirming a nonmalignant diagnosis or without lesion progression on radiographic follow-up were considered true-negative. Cases categorized as false-negative included those cases in which follow-up diagnostics revealed malignancy, lesion growth was noted on repeat diagnostic testing, death due to lung cancer within 12 months, treatment without a confirmed diagnosis or new diagnoses of cancer in the lung from any site. A total of 1215 individuals underwent an ENB aided procedure. A 12-month

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follow-up was completed on 80.3% (976/1215) of the participants. In those individuals who underwent lung lesion biopsy (n=1157), tissue was obtained in 94.4% of the cases (n=1092). Malignancy was diagnosed in 44.3% (484/1092) of the cases and was negative in 55.7% (608/1092) of the cases. At 12 months, the diagnostic yield was 72.9%. Sensitivity for malignancy was 68.8% (range: 59.9%-68.8%); the reported negative predictive value (NPV) was 56.3% (range: 46.7%-63.8%). The specificity and positive predictive value (PPV) were reported as 100% and the NPV was calculated at 56%. Further evaluation at 24 months will be performed and a recalculation of the indexes will be performed at that time. While the study evaluates a large population, the accuracy of these diagnostic indicators is limited by the significant loss to follow-up of approximately 20%.
McGuire and associates (2020) determined the comparative diagnostic accuracy, sensitivity, and negative predictive value for R-EBUS and ENB in sampling PPLs (peripheral pulmonary lesions). A total of 17 ENB and 24 R-EBUS studies were included with 2097 participants in the R-EBUS group and 1107 participants in the ENB group. While the authors concluded that both technologies have a high proportion of successful localization (90.2% versus 98.2%, respectively) with similar diagnostic accuracy for malignancy (72.4% versus 76.4%, respectively), the analysis is limited by a high amount of between-study heterogeneity and the overall poor methodological quality of the studies. The authors noted:

> Given the equipoise with respect to the overall diagnostic superiority of R-EBUS versus ENB, future prospective study in the form of a randomized trial comparing test performance of each technology for a sampling of PPLs compared with a well-defined reference standard is warranted.

The 2013 American College of Chest Physicians Evidence Based Guidelines includes a recommendation for electromagnetic navigation guidance:

> In patients with peripheral lung lesions difficult to reach with conventional bronchoscopy, electromagnetic navigation guidance is recommended if the equipment and the expertise are available (Grade 1C).

This recommendation is based on low quality evidence; higher quality evidence may impact confidence in this recommendation and may even change the estimate itself. Ost and colleagues (2016) noted that much of the data was obtained at centers of excellence with a carefully selected study population; it is uncertain how representative this study population is of the general population.

Fluoroscopic ENB

In an attempt to address the lack of real-time imaging, a limitation associated with ENB, digital tomosynthesis using conventional C-arm, or fluoroscopic ENB (F-ENB), was introduced as part of a software upgrade of the superDimension package. The ILLUMINSITE™ platform has been proposed as a means to mitigate CT body divergence, which is the difference between the location of the nodule on the pre-procedure CT scan and the location during the procedure. In addition to the total IV anesthesia associated with ENB, F-ENB requires neuromuscular blockade in order to capture the tomosynthesis images. Currently, the evidence regarding this new technology is limited to a retrospective study consisting of 67 nodules sampled using fluoroscopic ENB (Aboudara, 2020).

Fiducial Marker Placement or Pleural Dye Marking of Lung Nodule

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Fiducial markers (FM) are used as a means of motion management during gated stereotactic body radiation therapy (SBRT) for the treatment of non-small cell lung cancer. FMs can also be used as a visualization aid during surgery with or without pleural dye marking. FMs allow the operator to confirm correct positioning on the target center and to facilitate accuracy of high-dose radiation treatments to small targets and targets in close proximity organs. FMs are placed percutaneously with image guidance or through video bronchoscope. ENB has been proposed as an alternative method of FM placement that may result in fewer complications (Bowling, 2019).

Bowling and associates (2019) reviewed the safety and accuracy outcomes of ENB-guided FM placement in the participants of the NAVIGATE trial who underwent FM placement with the superDimension™ navigation system. The NAVIGATE trial, a prospective, multicenter, observational cohort study of ENB using the superDimension™ navigation system, included 258 adults who underwent elective FM placement. Concurrent procedures included FM placement and lung biopsy, FM placement and dye marking, FM placement alone and FM placement and dye marking and biopsy. The median overall procedure time was 57 minutes and 31 minutes for the ENB procedure; general anesthesia was used in 68.2% (176/258) of the cases. An average of 2.2 ± 1.7 FMs were placed in each session. A placement accuracy of 99.2% was based on subjective operator assessment, which authors admit may not be the most clinically appropriate indicator for SBRT success. When confirmed during follow-up imaging, 94.1% of the markers remained in place. Complication rates were reported as procedure-related pneumothorax rate 5.4% (14/258) overall, grade 2 or higher pneumothorax rate 3.1% (8/258) and respiratory failure rate 1.6% (4/258). Similar to the studies regarding ENB for biopsy, this study lacks a comparator group using an established means of FM placement.

Using data from the NAVIGATE trial, Bowling and colleagues (2019a) reported on the 1-month interim analysis of 23 individuals who underwent pleural dye marking prior to lung resection. The objective of the study was to evaluate usage patterns, techniques and performance. Dye marking was conducted alone or concurrently with lesion or lymph node biopsy and/or FM placement. Fluoroscopy was used in all cases, EBUS was used in 4/23 cases. Following dye marking, surgical resection was attempted in all cases and the surgeon considered pleural dye marking adequate in 21/23 cases (91.3%). The authors note, “The combined method of ENB, fluoroscopy and radial EBUS may be advantageous when indicated and available.” It is unclear what additional benefit ENB provides during pleural dye marking.

Yanagiya and associates (2020) performed a meta-analysis evaluating the safety and efficacy of preoperative bronchoscopic marking. The authors used pooled data from several methods as well as subgroup analyses on individual methods. The most common method evaluated, dye marking under ENB, was used in 15 of the 25 total studies included in the review. The subgroup analyses calculated in a successful marking rate for ENB of 0.94 (95% CI, 0.91-0.96), but reported significant heterogeneity. The successful resection rate for ENB was 0.99 (95% CI, 0.97-1.00). These results were similar to the pooled rates (0.97; 95% CI, 0.95-0.99 and 0.98; 95% CI, 0.96-1.00, respectively). While bronchoscopic marking in general and ENB in particular appeared to be effective and safe, the majority of studies in the meta-analysis were single armed retrospective observational studies with a limited number of participants. In addition, this analysis did not consider elements which could affect outcomes including characteristics of the nodules or the surgical procedure used.

Summary

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.
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There have been a number of prospective and retrospective studies evaluating the outcomes of ENB-guided lesion biopsy, (Bhatt, 2018; Bolton, 2014; Bolton, 2018; Gildea, 2006; Krimsky, 2013; Loo, 2014; Nabavizadeh, 2014; Odronic, 2014; Oh, 2021; Ozgul, 2016; Schwarz, 2006; Wilson, 2007). While the NAVIGATE study attempts to provide a real world, practical design, the results of the study are limited by the absence of a protocolized approach (Thiboutot, 2019). The overall methodological quality of the current body of evidence remains low as there are heterogeneity associated with defined outcomes such as diagnostic yield and sensitivity and negative likelihood ratio (NLR) outcomes (Gex, 2014; Zhang, 2015). There remains a lack of studies which include head-to-head comparisons of ENB with established biopsy techniques; the impact on care management and clinical outcomes is also unclear. Similarly, evidence evaluating the use of ENB to place surgical or radiological markers is limited by a lack of comparator groups. (Bolton, 2015; Bolton, 2017; Nabavizadeh, 2014; Schroeder, 2010).

Artificial Intelligence (AI) Tomography with Augmented Fluoroscopic Guidance

In 2018, the LungVision™ System (Body Vision Medical Inc., New York, NY) received FDA clearance as a tool, used with standard bronchoscopic instruments, to guide the instruments to the target area within the respiratory system. The approval is based upon a predicate guide sheath. The LungVision system provides guidance during a bronchoscopy via multi-modal image fusion of preoperative CT and interoperative fluoroscopy. This allows real-time augmented endobronchial fluoroscopic navigation and guidance. The initial LungVision device included multi-image fusion capabilities. LungVision's second generation system incorporated AI algorithms, C-arm based tomography (CABT) technology and navigation tool integration into the system (Pertzov, 2021).

Pertzov and colleagues (2018) evaluated the diagnostic yield and safety of the use of the LungVision system combined with transbronchial cryobiopsy in a prospective, single-center industry sponsored study. Individuals with peripheral pulmonary nodules (PPNs) on chest CT were included (n=63). The primary outcome was correct tissue diagnosis, defined as the number of tissue diagnoses, malignant or benign, with follow-up at 1 year that showed clinical or radiological improvement and no alternative diagnosis made. The results included nodules obtained with the first-generation device (n=30) and second-generation device (n=33). A correct diagnosis was obtained in 81.8% (27/33) of individuals using the first-generation device and 73.3% (22/30) of individuals using the second-generation device. In those PPNs smaller than 20 mm, the correct diagnosis was a combined 72.2% between the two systems. The cohort included 11 individuals with negative results initially but were found to be positive following rebiopsy using transthoracic needle aspiration (TTNA).

In a prospective, multicenter study, Cicenia and associates (2020) reported on the localization success rate and diagnostic yield of LungVision guided bronchoscopies. Individuals with suspicious nodules of any size or location were included (n=55); 2 individuals presented with two nodules. Successful localization was accomplished in 93% (57/53) of the cases. The rate of successful localization was not found to be dependent on nodule size, however, the diagnostic yield varied with nodule size. The overall diagnostic yield was reported at 75.4%. The biopsies were considered definitively diagnostic if the pathology results determined a sample to be malignant or benign on the day of the procedure. No follow-up was done on these samples. The applicability of these findings is limited as the authors noted that the LungVision system was continuously updated throughout the study period. These findings are preliminary and largely represent an evaluation of the technology itself. Additional studies with targeted populations and additional follow-up of diagnostic yield will be needed to evaluate the impact of this technology on clinical outcomes.

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Robotic assisted bronchoscopy

The Monarch® Platform (Auris Health Inc., Redwood City, CA) received FDA clearance on March 22, 2018. The system includes 2 robotic arms and the electronic systems used to operate the arms. Navigational support is provided by ENB using a CT scan obtained within 2 weeks pre-procedure. A flexible bronchoscopy is first performed to confirm the absence of endobronchial disease and provide topical anesthesia. The scope is then advanced using direct visualization, ENB and fluoroscopic guidance. Once the targeted location is reached, an R-EBUS probe is inserted into the working channel to view the area. Following R-EBUS visualization, TBNA is used to obtain samples from the targeted lesions (Chen, 2020).

The Ion™ Endoluminal System (Intuitive Surgical, Inc, Sunnyvale, CA) received clearance by the FDA in February 2019. The Ion System uses a CT scan and proprietary software to generate a 3D visualization of the airway to identify the nodule and map and save a pathway to the targeted nodule, which is loaded into the controller. This preloaded pathway and real-time vision using a fiberoptic shape sensor is used to provide location information while accessing the nodule. The catheter is locked in place once the nodule is accessed and a needle is advanced through the catheter to obtain the sample.

The BENEFIT study, a prospective, multicenter pilot and feasibility study evaluated the use of a robotic bronchoscopic system in accessing and obtaining peripheral pulmonary lesions (Chen, 2020). Individuals with peripheral pulmonary lesions 1 to 5 cm in size with no evidence of mediastinal or hilar lymph node disease were included (n=54). The primary efficacy point was confirmation of lesion localization with R-EBUS. Lesion localization with R-EBUS was confirmed in 96.2 % (51/53) of the cases. The diagnostic yield at 12-month follow-up was reported as 74.1% (40/54). Pneumothorax was reported in 3.7% (2/54) of the cases, 1 of which required tube thoracostomy. This study was designed to assess the safety and feasibility of using robotic bronchoscopy to assess peripheral lung nodules. The authors note that robotic bronchoscopic techniques are in the "early phases of exploration" and that in order to perform an appropriate assessment of robotic technology, additional studies that address diagnostic yield and related factors are needed.

The limited published literature regarding robotic bronchoscopy is comprised of prospective or retrospective reviews and case series (Chaddha, 2019; Fielding, 2019; Rojas-Solano, 2018; Simoff, 2021). The current evidence is lacking several components, including a comparator group, and long-term follow-up to better assess true diagnostic yield. Robotic bronchoscopy is in the early phases of use and development, and several drawbacks exist, including potentially increasing procedure time while not improving diagnostic accuracy (Kent, 2020).

Background/Overview

In 2021, lung cancer will be diagnosed in approximately 235,760 individuals in the United States and will cause an estimated 131,880 deaths (ACS, 2021). Lung cancer screening using low-dose CT of the chest is recommended in individuals considered at high risk (NCCN V1.2021). Over 25% of the computed tomography (CT) scans in the high-risk population will be abnormal. These screening CT chest scans can result in a high proportion of false-positive peripheral pulmonary lesions, up to 96.4% (McGuire, 2020). While early detection is integral to improved outcomes, false positive results can result in over-diagnosis and increased testing, including invasive testing. Invasive testing increases the risk of complications such as pneumothorax.

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Individuals with suspect nodules can undergo biopsy using several techniques, depending upon nodule location. Central masses may typically be biopsied by bronchoscopy or mediastinoscopy. Peripheral nodules may benefit from radial EBUS, endoscopic ultrasound or transthoracic needle aspiration (TTNA) (NCCN, V6.2021). ENB maps out the lungs and provides a visual pathway to the lesion and real-time information about the position of the catheter during the bronchoscopy. ENB is intended to enhance a standard bronchoscopy and to improve the diagnostic yield of transbronchial tools used during bronchoscopy procedures to sample peripheral parenchymal lung lesions not visible through the bronchoscope.

ENB is not a real-time procedure. A CT scan is performed on one day, with a single breath hold and the individual not moving, and on another day (or potentially later the same day) in another setting, the bronchoscopy is performed while the individual is awake and breathing with a bronchoscope placed in the airway, (which typically produces coughing and gagging to some extent). The importance of this difference is that the lesions detected on the single breath hold CT scan will not necessarily be in the same physical location as in a breathing individual during a bronchoscopy. This CT body divergence can be attributed to several factors including changes in positioning, muscle movement, atelectasis or the physiologic effects from general anesthesia (Kent, 2020). In a retrospective review, Chen and colleagues (2015) evaluated the records of 46 individuals with pulmonary lesions who had two pre-procedure CT scans performed prior to bronchoscopy, one CT scan at full inspiration and a second CT scan at end-exhalation during tidal volume breathing. The average motion of all 85 pulmonary lesions identified was 17.6 mm with lower lobe nodules showing significantly more movement than upper lobe nodules. The authors noted that the movement on planning chest CT scans could potentially significantly affect the diagnostic yield during ENB procedures.

When obtaining a biopsy, the size of the sample is important. A large sample size is valuable in malignant cases when additional testing, such as immunohistochemical and genetic analysis is needed. In benign cases, a large sample size gives the pathologist additional material to work with, potentially increasing the validity of the diagnosis (Pertzov, 2021).

The 2015 An Official American Thoracic Society Research Statement: A Research Framework for Pulmonary Nodule Evaluation and Management, was developed with the hope to "accelerate the pace and increase the efficacy of discovery to improve the quality of care for patients with pulmonary nodules". The statement includes the following recommendations:

- The efficacy and effectiveness of new diagnostic strategies (including novel imaging tests and biopsy techniques, biomarkers, and prognostic models) should be evaluated using established phases of test development, from identification of a novel strategy or characteristic to establishment of clinical utility.
- Tests and interventions should be evaluated for their impact on patient centered outcomes.

Definitions

Bronchoscopy: An endoscopic test that utilizes either a rigid or a flexible catheter, in order to visualize and collect samples (washing, brushing, biopsy, culture, etc.) from the endobronchial tubes/branches of the respiratory system.

Diagnostic yield: A subset of the overall yield of tissue obtained during bronchoscopy which results a positive or negative diagnosis.

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Navigational systems: Systems include a pre-operative imaging/planning component, which maps the intended course to the lesion. During the bronchoscopy, sensors attached to the bronchoscope allow for tracking of the catheter along the intended pathway. Use of navigational systems are intended to be used to access peripheral lung nodules and improve diagnostic yield.

Robotic bronchoscopy: A navigational bronchoscopy platform which includes a robotic arm, allowing the physician to interact with the bronchoscope through a controller arm. This direct interaction is thought to allow for more precise control by the operator.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation [add-on code]

ICD-10 Diagnosis

All diagnoses

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ig4 EndoBronchial System
iLogic Electromagnetic Navigation Bronchoscopy
ILLUMISITE™ (Medtronic, Minneapolis, MN)
Ion Endoluminal System
LungPoint Virtual Bronchoscopic Navigation
Monarch Platform
SpiN Drive System
superDimension/Bronchus inReach System

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.

Document History

Status	Date	Action
Revised	11/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Expanded position statement and title to remove Electromagnetic from Navigational Bronchoscopy and include all types of navigational bronchosopy. Updated Description, Rationale, Background/Overview, References and Index sections.
Reviewed	08/12/2021	MPTAC review. Updated Description, Rationale, Background/Overview, References, and Websites sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale, Background/Overview, References, and Websites sections.
Reviewed	08/22/2019	MPTAC review. Updated References and Websites sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Websites, and References sections.
Reviewed	11/03/2016	MPTAC review. Updated Rationale, Websites, and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Description, Rationale, Websites for Additional Information, and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale, and Reference sections.
Reviewed	11/14/2013	MPTAC review. Updated Rationale and References sections.
Reviewed	11/08/2012	MPTAC review. Updated References section.
Reviewed	11/17/2011	MPTAC review. Updated References section.
Revised	11/18/2010	MPTAC review. The brand name was removed from the position statement. Updated Rationale and References section.
Reviewed	11/19/2009	MPTAC review. Updated References section. Updated Coding section with 01/01/2010 CPT changes.
New	11/20/2008	MPTAC review. Initial document development.

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