

Subject: Wireless Esophageal pH Monitoring System (Bravo™)

Effective Date: 4/15/2006

Revision Date: 4/15/2007

Number: 0329

INSTRUCTIONS FOR USE

This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2007 Intracorp/CareAllies

Wireless esophageal pH monitoring (e.g., Bravo™ pH Monitoring System [Medtronic, Inc., Shoreview, MN]) is considered medically necessary as an alternative to catheter-based ambulatory pH monitoring for any ONE of the following:

- to document abnormal esophageal acid exposure in an endoscopy-negative patient being considered for surgical antireflux repair
- to evaluate patients after antireflux surgery who are suspected to have ongoing abnormal reflux
- to evaluate patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy
- to detect refractory reflux in patients with chest pain after cardiac evaluation and a four-week trial of PPI therapy
- to evaluate a patient with suspected otolaryngologic manifestations (e.g., laryngitis, pharyngitis, chronic cough) of gastroesophageal reflux disease (GERD) after symptoms have failed to respond to at least four weeks of PPI therapy
- to document concomitant GERD in an adult onset, nonallergic asthmatic suspected of having reflux-induced asthma who has failed at least four weeks of PPI therapy

General Background

Gastroesophageal reflux disease (GERD) is defined as symptoms or mucosal damage produced by the abnormal reflux of gastric contents into the esophagus (DeVault, et al., 2005). Approximately 44% of the United States population experience gastroesophageal symptoms at least once a month; 14% have weekly symptoms, and 7% have daily symptoms (Finks, et al., 2006).

The most common symptoms of GERD are heartburn, a sensation of substernal burning pain, and regurgitation of swallowed food. Other esophageal complaints may include a sensation of a foreign body in the posterior pharynx or excessive salivation. Difficulty, inability or pain with swallowing, bleeding, anemia, and weight loss are considered alarm symptoms. These alarm symptoms (e.g., malignancy, esophageal stricture) may suggest complicated disease and might require further evaluation (Finks, et al., 2006).

Although GERD is a chronic disease, it is generally treatable with medications and with changes in lifestyle and eating habits. Healthy patients with a classic history of uncomplicated reflux can be treated first with simple nonpharmacological measures and then with the addition of pharmacological intervention

(e.g., histamine 2 blockers, proton pump inhibitor [PPI]) as needed. In many instances, these measures will suffice. If the patient fails to respond, or if heartburn is complicated by dysphagia, weight loss or anemia, then a more comprehensive diagnostic investigation may be indicated. A detailed evaluation is especially important in older patients, in whom the risk for malignancy is increased because of the significant malignant potential associated with chronic GERD. **Screening** for Barrett's esophagus is recommended in persons who have had symptomatic GERD for at least five years (Richter, 2003; Ip, et al., 2005; Campion, 2006).

There is no gold standard test for the diagnosis of GERD because of the wide range of typical, atypical and extraesophageal symptoms that occur. The classical symptoms of heartburn and acid regurgitation are sufficient to identify reflux disease and to begin medical treatment, making testing often unnecessary. A careful patient history seeking typical symptoms of heartburn or regurgitation provides for the highest specificity, 89% and 95%, respectively, in the diagnosis of GERD (Richter, 2003).

Upper endoscopy is the current standard for documenting the type and extent of mucosal injury to the esophagus. It identifies the presence of esophagitis and excludes other causes of the patient's symptoms. However, only 40–60% of patients with abnormal esophageal reflux by potential of hydrogen (pH) testing have endoscopic evidence of esophagitis. Thus, the sensitivity of endoscopy for GERD is 60% at best, but it has excellent specificity, at 90–95% (Richter, 2003).

Ambulatory 24-hour catheter-based esophageal pH monitoring is currently the standard method for establishing pathological reflux in patients with GERD. The test involves the placement of a thin wire or catheter that is passed through the patient's nose or mouth to the lower esophagus at the area just above the stomach. The catheter is taped in place to the patient's nose and removed by the health care professional using simple traction on the catheter. The catheter is removed with minimal discomfort or complications. The catheter is attached to a small battery-powered data logger, which can be worn on the patient's belt. An event marker is activated in response to symptoms, meals and body position changes. Monitoring is usually carried out for a period of 18–24 hours. Reflux episodes are detected by a drop in pH to less than four. Additionally, patients are asked to keep a diary of GERD symptoms and activity. Once the monitoring period has been completed, the information from the logger is reviewed and compared to the diary information. Most adult patients may undergo this process during normal daily activities. However, infants and children may require hospitalization for esophageal pH monitoring (Richter, 2003).

An advantage of ambulatory esophageal pH monitoring is its ability to record and correlate symptoms with reflux episodes over extended periods. For this indication, it has essentially replaced the shorter acid perfusion Bernstein test. Among all the available tests, only ambulatory 24-hour esophageal pH monitoring provides direct evidence of GERD and remains the most specific test for GERD. Esophageal pH monitoring is recommended in patients without endoscopic evidence of esophagitis, those with extra-esophageal symptoms, those who have failed traditional anti-reflux therapies, and those who are potential candidates for anti-reflux surgery (DiMarino, et al., 2005; Richter, 2003).

The nasally passed pH catheter can be uncomfortable and embarrassing for some patients, causing them to restrict their normal daily activities. Discomfort from the catheter can result in abnormal eating, drinking, and sleeping patterns. The limitations to the patient's established routines may reduce reflux events. Test results may not reflect the severity of the disease. In addition, esophageal acid exposure may fluctuate from day to day. The 24-hour timeframe may not be an adequate exposure time to document symptoms for correlation with reflux events. Therefore, wireless pH monitoring (e.g., Bravo™ pH Monitoring System) was developed due to the limitations associated with catheter-based ambulatory 24-hour catheter-based pH monitoring (Tseng, et al., 2005; Pandolfino, et al., 2005; Hayes, 2005).

Bravo™ pH Monitoring System

The Bravo pH Monitoring System (Medtronic, Inc., Shoreview, MN) is a catheter-free or wireless diagnostic system that allows for the measurement of esophageal pH levels in patients who are experiencing or are suspected of having GERD. A gastroenterologist or endoscopist places the small Bravo pH capsule with enclosed sensor orally or transnasally via a delivery system during an endoscopy procedure. Once the capsule is advanced to the proper location within the esophagus, suction is applied, filling the capsule's suction chamber with esophageal tissue. The safety pin is removed and the locking

pin is advanced, which will securely attach the capsule to the wall of the esophagus. The sensor monitors and transmits esophageal pH levels every six seconds and every 12 seconds transmits the readings via radiofrequency to an external, pager-sized receiver for a period of 48 hours. The maximum range for the receiver is 3–5 feet. Following the study, normal functions such as swallowing and passage of food will cause the capsule to slough off and release spontaneously from the esophagus and pass through the digestive tract after several days. Early dislodgement of the capsule has been reported to range from 0%–4% and is recognized during review of the pH tracing. When the study is completed, the patient returns the receiver to the hospital or clinic where the data is downloaded to a computer which provides a report for patient diagnosis. The patient keeps a diary of their symptoms, which is correlated with the data from the receiver to gauge the extent and nature of the patient's GERD (Medtronic, 2004; Pandolfino, et al., 2005).

Potential complications of the nasal insertion method for the Bravo pH capsule include, but are not limited to, sore throat, trauma to the nasopharynx, and bloody nose. Potential complications of the oral insertion method for the Bravo pH capsule are those associated with upper gastrointestinal endoscopy. They include, but are not limited to, perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, cardiac arrhythmia or arrest. Potential complications associated with the Bravo pH Capsule with Delivery System include, but are not limited to: premature detachment of the pH capsule, failure of the pH capsule to detach from the esophagus within several days after placement, and discomfort associated with the pH capsule requiring endoscopic removal (Medtronic, 2004). In a study by Prakash et al. (2006), endoscopic removal of the Bravo capsule was required in < 2% of the patients (n=452) who underwent wireless pH monitoring. Severe chest pain was the main complaint in patients who required capsule removal.

The Bravo pH test is contraindicated in patients with bleeding diathesis, strictures, severe esophagitis, varices, obstructions, pacemakers, or implantable cardiac defibrillators. Additionally, because the Bravo capsule contains a small magnet, patients are restricted from undergoing a magnetic resonance imaging (MRI) study within 30 days of a Bravo procedure (Medtronic, 2004).

U.S. Food and Drug Administration (FDA)

The Bravo pH Monitoring System was granted 510(k) approval by the FDA in September 2000. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness in the form of clinical studies of the Bravo pH monitoring system prior to marketing the device. According to the FDA 510(k) Summary, device manufacturer submission of performance data was not required by the FDA. The FDA determined that the Bravo pH Monitoring System was substantially equivalent in materials, design and intended use to the following predicate devices (FDA, 2000):

Medtronic Functional Diagnostics' Zinetics 24™ Single-Use pH Catheter; Sandhill Scientific's ComforTEC Single-Use Internal References pH Probe; Medtronic Functional Diagnostics/Synectics' Digitrapper Mk III; Sandhill Scientific's BioSTAR pH Monitoring System; and Medtronic Functional Diagnostics Synectics' EsopHogram Reflux Analysis Module of Polygram for Windows (FDA, 2000). The Bravo pH Monitoring System is indicated for the use of gastroesophageal pH measurement and monitoring of gastric reflux disease.

Literature Review

Technical Feasibility, Safety and Tolerability of Wireless Esophageal pH Monitoring: Bhat et al. (2006) prospectively enrolled 217 patients with suspected GERD symptoms in a research registry to assess the feasibility and safety of wireless pH monitoring with the Bravo pH system. All patients for a

12-month period from April 2004 were enrolled. Successful completion was defined as at least 24 hours of pH recording. Safety data was obtained by review of patient diaries. The pH study was successfully completed in 95.1% of the patients. Early capsule detachment was reported in seven patients. Two patients had their receivers malfunction. No adverse events were reported. Eighteen patients had significant chest discomfort resulting in removal of the capsule in three patients. Of the completed studies, 56% were abnormal, with 32.2% abnormal on both days. Increased acid exposure was 16.1% on day one and 6.9% on day two. The authors caution that the increase in acid reflux early may be influenced by the technique (i.e., endoscopy and associated premedication) rather than a physiological abnormality which needs to be considered when pH data is analyzed.

In a prospective study, Belafsky et al. (2004) evaluated unsedated transnasal wireless pH capsule placement. Data concerning patient tolerance, success of capsule placement and function, complications, and pH recordings were evaluated in 46 patients. The indications for the procedure were chronic cough, GERD, and laryngopharyngeal reflux. Eleven percent of the recordings were performed on antireflux medications. Eighty-five percent of the procedures had successful placement of the capsule. Seven procedures failed due to inability to pass the capsule due to a tight nasal vault, early detachment or failure of the device, inability to complete the procedure due to laryngospasm, and loss of the data recorder after successful capsule placement. Patient tolerance was excellent. The mean number of reflux episodes per two-day study period was 121 (± 89), and the mean percentage of time the pH was <4 was 7.5 ($\pm 7.8\%$). Complications included epistaxis (2/46), laryngospasm (2/46), and vasovagal reaction (1/46).

Ward et al. (2004) evaluated the use of the wireless pH monitoring system in 60 patients with GERD or noncardiac chest pain. All patients underwent esophageal endoscopy and attempted attachment of a wireless Bravo pH system. Immediately after attachment, capsule placement was assessed endoscopically. The results of the study showed that adequate diagnostic data were obtained in 97% of the cases. However, in 12% ($n=7$) of the patients, the initial implantation attempt failed. A second attempt was successful in 86% of these patients. The researchers concluded that the study was limited by small sample size, retrospective analysis, failure to compare wireless monitoring with conventional transnasal monitoring, and failure to document the sensitivity and specificity of wireless pH monitoring for detection of GERD.

In a prospective randomized trial, Wong et al. (2005) compared the feasibility and tolerability of the traditional esophageal pH probe versus transnasal/per-oral placement of the wireless pH capsule ($n=50$). Patients recorded their food consumption, activities, symptoms, satisfaction with the test and completed a quality of life questionnaire. Patients with the wireless pH capsule reported less runny nose, nose and throat pain, throat discomfort and headache compared with the traditional probe. More chest pain was reported in the wireless pH capsule group. Placement of the wireless pH capsule was feasible in 92.6% of the cases, while 20% required per-oral insertion after transnasal placement due to patient discomfort and blockage of the passage, likely due to the size of the capsule. There was no difference in 24-hour esophageal pH results between the traditional pH probe and the wireless pH capsule for patients on and off PPI therapy.

Wenner et al. (2005) investigated the feasibility, safety, and normal values for esophageal acid exposure using the Bravo wireless esophageal pH monitoring system. This is the first study to establish normal values for esophageal acid exposure in a large age- and gender-matched healthy population. Fifty-seven asymptomatic patients had upper gastrointestinal endoscopy with transoral placement of the Bravo capsule 6 cm above the squamocolumnar junction. Seven patients were excluded from the study due to either capsule dysfunction or esophagitis. Twenty-five men and 25 females with a median age of 42 years were included in the study. All Bravo capsules were implanted with no complications. During pH monitoring, two capsules prematurely detached after 32 and 36 hours. The median percentage time with esophageal pH of < 4 was 0.7% on day one and 1.0% on day two ($p=0.033$), and the 95th percentile for the 48-hour recordings was 4.4%. The authors concluded ambulatory pH monitoring using the Bravo system is safe and feasible. Further studies are needed to define the sensitivity and specificity of the Bravo test in a reflux population. The patients' subjective experiences in comparison with available methods are unknown and have yet to be confirmed.

In a randomized crossover trial, Wenner et al. (2007) evaluated and compared the subjective experience of patients undergoing both 24-hour catheter-based and 48-hour wireless pH tests. All of the patients ($n=31$) answered a questionnaire which described the perceived severity of symptoms and the degree of interference with normal daily activities during the pH tests. The authors report that the severity of all adverse symptoms associated with wireless pH monitoring was significantly lower compared to the catheter-based technique. Wireless pH recording was associated with less interference with normal activities of daily living. Eighty-seven percent of the patients stated they would undergo wireless testing over catheter-based pH testing.

Pandolfino et al. (2005) compared esophageal acid exposure during simultaneous esophageal pH studies using the Bravo wireless system and a catheter-based monitoring system in 25 healthy asymptomatic individuals. One patient did not tolerate the catheter secondary to discomfort, and in two patients the

hardware malfunctioned in both systems. When the devices were appropriately adjusted using samples of known pH, the two devices produced similar mean pH values. The acid exposure recorded by the two devices was statistically similar.

Sensitivity and Specificity of Esophageal pH Monitoring: In a combined prospective study and retrospective case-matched controlled trial, Pandolfino et al. (2003) compared outcomes for a wireless pH monitoring group of 14 GERD patients and 15 healthy, asymptomatic patients with outcomes for a traditional transnasal pH monitoring group of 30 symptomatic patients matched by age and sex to the group of patients undergoing wireless monitoring. The wireless monitoring group had statistically significant improvements in throat comfort, patient satisfaction, and maintenance of normal diet and daily activities. However, the transnasal monitoring group had statistically significant improvements in esophageal comfort. This study also evaluated the sensitivity and specificity of wireless esophageal pH monitoring for the detection of GERD, relying on diagnoses that were determined before the study began. Wireless pH monitoring had a sensitivity of 68% and specificity of 90% if pH data from the first 24 hours of monitoring were used. If 48 hours of pH data were used, specificity increased to 95%, but sensitivity decreased to 65%. In contrast, when pH data were taken only from the day having the largest number and severity of esophageal acid exposures, the sensitivity increased to 84%, but specificity decreased to 85%. The researchers concluded that this is not a well-supported study, due to small sample size and because the sensitivity and specificity of transnasal esophageal pH monitoring for GERD detection was not reported.

24- Versus 48-Hour Esophageal pH Monitoring: Tseng et al. (2005) evaluated 48-hour wireless data from 190 recordings in 186 patients at three tertiary care referral centers. Abnormal esophageal acid exposure (AEAE) was defined by a Johnson-DeMeester score greater than 14.7 and was obtained in 115 studies (61%). The authors concluded that 48-hour pH testing may increase detection accuracy and sensitivity for AEAE by as much as 22%. Further research is needed to determine the appropriate threshold values for the Bravo probe and the usefulness for directing the treatment of GERD.

Prakash and Clouse (2005) examined the value of two- versus one-day esophageal pH monitoring in the detection of AEAE and reflux symptom association (n=157). Acid exposure time, symptom index, and a measure of reflux-associated symptom probability were calculated after one day of recording time and compared to the final results from two days of analysis. The evaluation of symptomatic patients for evidence of GERD was improved in several ways by extending recording time to two days with a wireless pH monitoring system. Patients recording symptoms increased by 6.8% when the monitoring was extended, and for patients off antireflux therapy, the proportion of subjects with abnormal acid exposure was increased by 12.4%. The authors stated further investigation will be required to demonstrate the clinical advantages toward directing therapy or predicting treatment outcomes.

Evidence-Based Review: An assessment of the evidence supporting catheterless esophageal pH monitoring by the National Institute for Health and Clinical Excellence (NICE, 2006) concluded: "Current evidence on the safety and efficacy of catheterless esophageal pH monitoring appears adequate to support the use of this technique provided that normal arrangements are in place for consent, audit and clinical governance." The authors stated that catheterless pH monitoring would be particularly appropriate in children and other patients who may not tolerate the nasal intubation required for catheter-based monitoring. Additionally, catheterless pH monitoring may be unsuitable for some patients (e.g., patients with pacemakers).

Professional Societies/Organizations

In 2005, the American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee developed a status evaluation report to address the use of the Bravo System for investigation of suspected reflux disease. The authors state that when the Bravo capsule is successfully attached, recording of esophageal pH is accomplished in 98% of cases. Premature dislodgement with prolonged intragastric recording is occasionally seen. The overall success during one- and two-day studies is 96% and 89%, respectively. The committee concluded that wireless esophageal pH monitoring offers a safe and comfortable alternative to pH monitoring by conventional transnasal systems. Patients are generally able to maintain normal activity and dietary intake during the testing. A pilot study revealed that catheter-based pH monitoring and Bravo pH monitoring were comparable in quantifying esophageal-acid exposure. The

normal values for esophageal pH exposure during the wireless pH monitoring needs to be confirmed (Chotiprashidi, et al., 2005).

In 2005, the American College of Gastroenterology (ACG) updated their 1999 recommended guidelines for the diagnosis and treatment of GERD. The guideline states that ambulatory reflux monitoring of the esophagus helps to confirm GERD in patients with persistent typical and atypical symptoms without evidence of mucosal damage, especially when a trial of acid suppression has failed. Additionally, it may be used to monitor the control of reflux in patients with continued symptoms on therapy. The ACG guidelines refer to wireless esophageal pH monitoring as a new technology that may alter the management of GERD. The device allows for monitoring of the esophageal mucosa without the discomfort of a nasoesophageal tube. The advantages are a decrease in patient discomfort, longer monitoring, and accuracy may be improved by allowing the patient to carry on their usual activities (DeVault and Castell, 2005).

In 1996, the American Gastroenterological Association (AGA) issued guidelines on the use of esophageal pH recording. The developers reviewed the guidelines in 2001, and the guidelines are current. The guidelines do not specifically address the use of wireless esophageal pH monitoring.

The AGA guidelines for the clinical use of esophageal pH recording recommend:

- Esophageal pH recording is indicated to document AEAE in an endoscopy-negative patient being considered for surgical antireflux repair (pH study done after withholding antisecretory drug regimen for \geq one week).
- Esophageal pH recording is indicated to evaluate patients after antireflux surgery who are suspected to have ongoing abnormal reflux (pH study done after withholding antisecretory drug regimen for \geq one week).
- Esophageal pH recording is indicated to evaluate patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to PPI (pH study done after withholding antisecretory drug regimen for \geq one week if the study is done to confirm excessive acid exposure or while taking the antisecretory drug regimen if symptom-reflux correlation is to be scored).
- Esophageal pH recording is possibly indicated to detect refractory reflux in patients with chest pain after cardiac evaluation using a symptom reflux association, preferably the symptom association probability calculation (pH study done after a trial of PPI therapy for at least four weeks).
- Esophageal pH recording is possibly indicated to evaluate a patient with suspected otolaryngologic manifestations (laryngitis, pharyngitis, chronic cough) of GERD after symptoms have failed to respond to at least four weeks of PPI therapy (pH study done while the patient continues taking their antisecretory drug regimen to document the adequacy of therapy).
- Esophageal pH recording is possibly indicated to document concomitant GERD in an adult onset, nonallergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding antisecretory drugs for \geq one week). Note: a positive test does not prove causality.
- Esophageal pH recording is not indicated to detect or verify reflux esophagitis (this is an endoscopic diagnosis) or to evaluate for "alkaline reflux."

Summary

Studies in the peer-reviewed scientific literature have reported that wireless esophageal pH monitoring is a safe and well-tolerated method to measure abnormal esophageal acid exposure. Professional society guidelines refer to wireless esophageal potential of hydrogen (pH) monitoring as a new technology that may alter the management of gastrointestinal reflux disease (GERD). Wireless esophageal pH monitoring offers a safe alternative to patients who cannot tolerate conventional catheter-based esophageal pH

monitoring systems. The reported advantages of wireless pH monitoring are a decrease in patient discomfort, longer monitoring, and the potential to improve accuracy by allowing the patient to perform their normal daily activities.

Whether the Bravo pH monitoring system is preferred over the conventional catheter-based pH monitoring for diagnostic evaluation depends on possible contraindications for both systems.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

When medically necessary:

CPT®*	Description
91034	Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
530.11	Reflux esophagitis
530.81	Esophageal reflux

*Current Procedural Terminology (CPT®) © 2006 American Medical Association: Chicago, IL.

References

1. Ahlwat SK, Novak DJ, Williams DC, Maher KA, Barton F, Benjamin SB. Day-to-day variability in acid reflux patterns using the BRAVO pH monitoring system. *J Clin Gastroenterol.* 2006 Jan;40(1):20-4.
2. American Gastroenterological Association (AGA) medical position statement: guidelines on the use of esophageal pH recording. Approved by the AGA Patient Care Committee 1996 Jan 25 and by the AGA Governing Board 1996 Feb 3. *Gastroenterology.* 1996 Jun;110(6):1981-96 (reviewed 2001).
3. Belafsky PC, Allen K, Castro-Del Rosario L, Roseman D. Wireless pH testing as an adjunct to unsedated transnasal esophagoscopy: the safety and efficacy of transnasal telemetry capsule placement. *Otolaryngol Head Neck Surg.* 2004;131(1):26-8.
4. Bhat YM, McGrath KM, Bielefeldt K. Wireless esophageal pH monitoring: new technique means new questions. *J Clin Gastroenterol.* 2006 Feb;40(2):116-21.
5. Champion FX, Richter JM. Approach to the patient with heartburn and reflux (gastroesophageal reflux disease). In: Goroll AG, Mulley, AG, editors. *Primary care medicine.* Philadelphia, PA: Lippincott Williams & Wilkins; 2007. Ch 61. p. 455-9.

6. Centers for Medicare & Medicaid Services. NCD for 24-Hour Ambulatory Esophageal pH Monitoring (100.3). Accessed February 28, 2007. Available at URL address: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd#PW
7. Chotiprashidi P, Liu J, Carpenter S, Chuttani R, DiSario J, Hussain N, et al. ASGE Technology Status Evaluation Report: wireless esophageal pH monitoring system. *Gastrointest Endosc.* 2005 Oct;62(4):485-7.
8. CIGNA Government Services. Implanted capsule pH monitoring for GERD (A2753). Article Revision Effective September 19, 2003. Accessed February 28, 2007. Available at URL address: <http://www.cignamedicare.com/articles/July05/Cope2756.html>
9. des Varannes SB, Mion F, Ducrotte P, Zerbib F, Denis P, Ponchon T, et al. Simultaneous recordings of oesophageal acid exposure with conventional pH monitoring and a wireless system (Bravo). *Gut.* 2005 Dec;54(12):1682-6. Epub 2005 Apr 20.
10. DeVault KR, Castell DO; American College of Gastroenterology. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Am J Gastroenterol.* 2005 Jan;100(1):190-200.
11. DiMarino AJ Jr, Cohen S. Clinical relevance of esophageal and gastric pH measurements in patients with gastro-esophageal reflux disease (GERD). *Curr Med Res Opin.* 2005 Jan;21(1):27-36.
12. Fajardo NR, Wise JL, Locke GR 3rd, Murray JA, Talley NJ. Esophageal perforation after placement of wireless Bravo pH probe. *Gastrointest Endosc.* 2006 Jan;63(1):184-5.
13. Finks JF, Hunter JG. Gastroesophageal reflux disease. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy 2006.* 58th ed. St. Louis, MO: W.B. Saunders Co.; 2006. Section 7.
14. Gonzalez JO, Barkin JS. Endoscopic visualization of deployment of the Bravo pH System to prevent malplacement. *Gastrointest Endosc.* 2005 Jul;62(1):178-80.
15. HAYES Medical Technology Directory™. Wireless Esophageal pH Monitoring. Lansdale, PA: HAYES, Inc.; ©2003 Winifred S. Hayes, Inc. 2004 Nov. Update search Dec 2006.
16. HAYES health technology brief. Wireless Esophageal pH Monitoring (Bravo™ pH Monitoring System) (Medtronic Gastroenterology) for Gastroesophageal Reflux Disease. Lansdale, PA: HAYES, Inc.; ©2005 Winifred S. Hayes, Inc. June 20, 2005.
17. Institute for Clinical Systems Improvement. Health Care Guideline: Dyspepsia and GERD. 7th ed. July 2006. Accessed February 28, 2007. Available at URL address: http://www.icsi.org/knowledge/browse_category.asp?catID=29&StartAlpha=D&EndAlpha=D&page=1
18. Ip S, Bonis P, Tatsioni A, Raman G, Chew P, Kupelnick B, et al. Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease. Evidence Report/Technology Assessment No. 1. (Prepared by Tufts-New England Medical Center Evidence-based Practice Center under Contract No. 290-02-0022.) Rockville, MD: Agency for Healthcare Research and Quality. December 2005. Accessed March 1, 2007. Available at URL address: <http://effectivehealthcare.ahrq.gov/aboutUs/index.cfm>
19. Lee YC, Wang HP, Chiu HM, Huang SP, Tu CH, Wu MS, Lin JT. Patients with functional heartburn are more likely to report retrosternal discomfort during wireless pH monitoring. *Gastrointest Endosc.* 2005 Dec;62(6):834-41.

20. Medtronic, Inc. What is the Bravo™ pH monitoring system? Version 83.01. 2004. Accessed February 28, 2007. Available at URL address: <http://www.medtronic.com/neuro/gerd/whatisBravo.html>
21. National Institute for Health and Clinical Excellence (NICE). Catheterless esophageal pH monitoring. July 2006. Accessed February 27, 2007. Available at URL address: <http://www.nice.org.uk/page.aspx?o=ipg187guidance>
22. [No authors listed]. Special report: wireless esophageal pH monitoring. Technol Eval Cent Asses Program Exec Summ. 2006 May;21(2):1-2. Accessed February 27, 2007. Available at URL address: <http://www.bcbs.com/betterknowledge/tec/>
23. North American Society for Pediatric Gastroenterology and Nutrition. Pediatric GE Reflux Clinical Practice Guidelines. 2001. Accessed February 28, 2007. Available at URL address: <http://www.naspgan.org/sub/positionpapers.asp>
24. Numans ME, Lau J, de Wit NJ, Bonis PA. Short-term treatment with proton-pump inhibitors as a test for gastroesophageal reflux disease: a meta-analysis of diagnostic test characteristics. *Ann Intern Med*. 2004 Apr 6;140(7):518-27.
25. Pandolfino JE, Schreiner MA, Lee TJ, Zhang Q, Boniquit C, Kahrilas PJ. Comparison of the Bravo wireless and Digitrapper catheter-based pH monitoring systems for measuring esophageal acid exposure. *Am J Gastroenterol*. 2005 Jul;100(7):1466-76.
26. Pandolfino JE, Zhang Q, Schreiner MA, Ghosh S, Roth MP, Kahrilas PJ. Acid reflux event detection using the Bravo wireless versus the Slimline catheter pH systems: why are the numbers so different? *Gut*. 2005 Dec;54(12):1687-92.
27. Pandolfino JE, Kahrilas PJ. Prolonged pH monitoring: Bravo capsule. *Gastrointest Endosc Clin N Am*. 2005 Apr;15(2):307-18.
28. Pandolfino JE, Richter JE, Ours T, Guardino JM, Chapman J, Kahrilas PJ. Ambulatory esophageal pH monitoring using a wireless system. *Am J Gastroenterol*. 2003 Apr;98(4):740-9.
29. Prakash C, Clouse RE. Value of extended recording time with wireless pH monitoring in evaluating gastroesophageal reflux disease. *Clin Gastroenterol Hepatol*. 2005 Apr;3(4):329-34.
30. Prakash C, Jonnalagadda S, Azar R, Clouse RE. Endoscopic removal of the wireless pH monitoring capsule in patients with severe discomfort. *Gastrointest Endosc*. 2006 Nov;64(5):828-32.
31. Richter JE. Gastroesophageal reflux disease. In: Yamada T, Alpers DH, Lane L, Owyang C, Powell DW, editors. *Textbook of Gastroenterology*. 4th ed. Philadelphia, PA; Lippincott, Williams & Wilkins; 2003 May 1. Ch 60.
32. Streets CG, DeMeester TR. Ambulatory 24-hour esophageal pH monitoring: why, when, and what to do. *J Clin Gastroenterol*. 2003 Jul;37(1):14-22.
33. Tseng D, Rizvi AZ, Fennerty MB, Jobe BA, Diggs BS, Sheppard BC, Gross SC, Swanstrom LL, White NB, Aye RW, Hunter JG. Forty-eight-hour pH monitoring increases sensitivity in detecting abnormal esophageal acid exposure. *J Gastrointest Surg*. 2005 Nov;9(8):1043-51; discussion 1051-2.
34. Tu CH, Lee YC, Wang HP, Wu MS, Chiu HM, Lin JT. Ambulatory esophageal pH monitoring by using a wireless system: a pilot study in Taiwan. *Hepatogastroenterology*. 2004 Nov-Dec;51(60):1586-9.

35. U.S. Food and Drug Administration (FDA). 510(k) summary: Bravo pH Monitoring System. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). 2000 Sep. Accessed February 28, 2007. Available at URL address: <http://www.fda.gov/cdrh/pdf/k002028.pdf>
36. Ward EM, DeVault KR, Bouras EP, Stark ME, Wolfsen HC, Davis DM, et al. Successful esophageal pH monitoring with a catheter-free system. *Aliment Pharmacol Ther.* 2004 Feb 15;19(4):449-54.
37. Wenner J, Johnsson F, Johansson J, Oberg S. Wireless oesophageal pH monitoring: feasibility, safety and normal values in healthy subjects. *Scand J Gastroenterol.* 2005 Jul;40(7):768-74.
38. Wenner J, Johnsson F, Johansson J, Oberg S. Wireless Esophageal pH Monitoring Is Better Tolerated than the Catheter-Based Technique: Results from a Randomized Cross-Over Trial. *Am J Gastroenterol.* 2007 Feb;102(2):239-45.
39. Wong WM, Bautista J, Dekel R, Malagon IB, Tuchinsky I, Green C, et al. Feasibility and tolerability of transnasal/per-oral placement of the wireless pH capsule vs. traditional 24-h oesophageal pH monitoring--a randomized trial. *Aliment Pharmacol Ther.* 2005 Jan 15;21(2):155-63.
40. Yamaguchi T, Seza A, Odaka T, Shishido T, Ai M, Gen S, et al. Placement of the Bravo wireless pH monitoring capsule onto the gastric wall under endoscopic guidance. *Gastrointest Endosc.* 2006 Jun;63(7):1046-50.