



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Wireless Esophageal pH Monitoring System (Bravo™)**

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Capsule Endoscopy
Endoscopic Anti-Reflux Procedures
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INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers wireless esophageal pH monitoring (e.g., Bravo™ pH Monitoring System [Given®, Imaging, Duluth, MN]) (Current Procedural Terminology [CPT] code 91035) as medically necessary for ANY of the following indications:

- documentation of abnormal esophageal acid exposure in an endoscopy-negative individual being considered for surgical antireflux repair
- evaluation of an endoscopy-negative individual with typical reflux symptoms refractory to proton pump inhibitor (PPI) therapy
- documentation of adequacy of PPI therapy in esophageal acid control in an individual with known complications of reflux disease such as Barrett's esophagus
- evaluation of an endoscopy-negative individual with atypical reflux symptoms refractory to twice per day PPI therapy
- evaluation following antireflux surgery of ongoing abnormal reflux that has not responded to empiric trials of PPI therapy

CIGNA does not cover wireless esophageal pH monitoring for EITHER of the following indications because it is considered experimental, investigational or unproven:

- detection or verification of reflux esophagitis
- evaluation for "alkaline reflux"

General Background

Ambulatory 24-hour catheter-based esophageal potential of hydrogen (pH) monitoring is currently the standard method for establishing pathological reflux in patients with gastroesophageal reflux disease (GERD). 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 (Richter, 2010, Tseng, et al., 2005; Pandolfino, et al., 2005b).

Bravo™ pH Monitoring System

The Bravo pH Monitoring System (Given® Imaging, Duluth, 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 (Given Imaging, 2011; Pandolfino, et al., 2005b).

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 (Given Imaging, 2011). 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.

It is recommended that tracings that show prolonged acid exposure or loss of communication with the Bravo capsule should be screened for the capsule's possible early dislodgement and premature advancement into the stomach (Iqbal, et al., 2007).

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 (Given Imaging, 2011).

U.S. Food and Drug Administration (FDA)

The Bravo pH Monitoring System was granted 510(k) approval by the FDA in September 2000. The Bravo pH Monitoring System is indicated for the use of gastroesophageal pH measurement and monitoring of gastric reflux disease (FDA, 2000).

Literature Review

Although no large, prospective, controlled trials with reported long-term health outcomes have been performed to compare the diagnostic and therapeutic utility of wireless pH monitoring with conventional transnasal pH monitoring, wireless esophageal pH monitoring has become an alternative to a subset of patients who cannot tolerate conventional catheter-based esophageal pH monitoring systems. The reported major advantages of wireless esophageal pH monitoring to conventional catheter-based esophageal monitoring is 48 hours of monitoring and patient tolerability.

Sensitivity and Specificity of Wireless Esophageal pH Monitoring: In a combined prospective study and retrospective case-matched controlled trial, Wenner et al. (2007b) studied the optimal thresholds for sensitivity and specificity for wireless 48-hour pH monitoring in patients with GERD. Patients with typical reflux symptoms and a distinct response to acid suppressive medication underwent endoscopy followed by 48-hour wireless esophageal pH studies with the pH electrode placed 6 cm above the squamocolumnar junction. The results were compared to those obtained in 55 healthy controls. Sensitivity, specificity, and thresholds for esophageal acid exposure were analyzed using receiver operating characteristic (ROC) curves. The patient population consisted of 64 patients, 25 women and 39 men, with a median age of 48 yr. Analysis of the area under the ROC curve showed that, for all patients as well as for subgroups of patients with (n=33) and without (n=31) esophagitis, the total percent time with pH < 4 for the 48-hour study period was the best parameter to discriminate patients from controls. Analysis of acid exposure for day one, day two, or using the day with the highest acid exposure did not improve the diagnostic accuracy. A test specificity in the range of 90–95% resulted in a cutoff level of 3.6–4.4% of the total time with pH < 4 for the 48-hour period. This threshold generated a test sensitivity of 59–64% in all patients, 76–79% for patients with esophagitis and 42–48% in patients with no esophagitis. The total percentage of time that esophageal pH was < 4 for the entire 48-hour study period was the parameter that best discriminated patients with typical reflux symptoms from healthy controls, and to achieve a specificity of 90–95% a cutoff level of 4% is recommended.

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.

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

American College of Gastroenterology (ACG): In 2007, the ACG updated their 1996 clinical applications of ambulatory esophageal pH monitoring (Hirano and Richter, 2007). In the 2007 guidelines, the ACG states that newer techniques for esophageal function testing such as wireless pH capsule monitoring, duodenogastroesophageal reflux detection (formerly referred to as alkaline or bile reflux), and esophageal impedance testing have been introduced over the past decade and are currently available in clinical practice. The ACG guidelines state, “Appropriate and careful patient selection with judicious use of preoperative reflux testing combined with a high success rate for fundoplication makes the need for postoperative reflux testing uncommon. pH monitoring is appropriate in the evaluation of postfundoplication patients with reflux symptoms

who have not responded to empiric trials of proton pump inhibitor (PPI) therapy. Dysphagia, abdominal or chest pain, or dyspeptic symptoms in postfundoplication patients are generally best evaluated with barium studies, endoscopy, and esophageal manometry.”

The ACG guidelines for the clinical use of ambulatory esophageal pH monitoring, impedance monitoring, and bile reflux testing recommend:

pH monitoring is useful:

- Document abnormal esophageal acid exposure in an endoscopy-negative patient being considered for endoscopic or surgical antireflux procedure. An abnormal pH study does not, however, causally link reflux with a specific presenting symptom. Use of symptom association analyses provide information in this regard but have not been adequately validated.
- Evaluation of endoscopy-negative patients with typical reflux symptoms which are refractory to proton pump inhibitor (PPI) therapy.
 - pH study done on-therapy but consider extended testing with wireless pH system incorporating periods of both off- and on-therapy testing. The diagnostic yield of on-therapy testing in patients who have not symptomatically responded to twice per day PPI therapy is limited.
 - Use of a symptom correlation measure (symptom index [SI], symptom sensitivity index [SSI], or symptom association probability [SAP]) is recommended to statistically interpret the causality of a particular symptom with episodes of acid reflux. Such measures can be applied even in the presence of esophageal acid exposure values that fall within the normal range. These statistical measures, however, do not ensure a response to either medical or surgical antireflux therapies. The yield of symptom association is increased when pH study is done for 48 hours and off PPI therapy compared with 24 hour and on PPI therapy, respectively.
 - Routine proximal or intragastric pH monitoring not recommended.

pH monitoring may be useful:

- Document adequacy of PPI therapy in esophageal acid control in patients with complications of reflux disease that include Barrett's esophagus. The threshold for adequate suppression of esophageal acid exposure on PPI therapy has not been defined. Furthermore, data supporting the clinical importance of achieving normalization of esophageal acid exposure in such patients are limited.
- Evaluation of endoscopy-negative patients with atypical reflux symptoms which are refractory to twice daily PPI therapy. The diagnostic yield of pH testing under such circumstances is low.
 - pH study done on b.i.d. PPI therapy in patients with high pretest probability of GERD or off therapy in patients with low pretest probability of GERD. Pretest probability is based on prevalence of GERD in patient population under question, clinician's impression, and degree of response to empiric PPI trial. Consider extended pH study to incorporate periods both off and on PPI therapy.
 - Use of symptom correlation recommended for selected symptoms that include chest pain. Use of symptom correlation in the evaluation of chronic laryngeal symptoms, asthma, and cough is of unproven benefit.
 - Routine proximal or intragastric pH monitoring not recommended.

Combined pH monitoring with esophageal impedance monitoring may be useful:

- Evaluation of endoscopy-negative patients with complaints of heartburn or regurgitation despite PPI therapy in whom documentation of nonacid reflux will alter clinical management. The increased diagnostic yield of impedance monitoring over conventional pH monitoring for symptom association is highest when performed on PPI therapy and nominal off PPI therapy.
- Utility of impedance monitoring in refractory reflux patients with primary complaints of chest pain or extraesophageal symptoms is unproven.
- Current interpretation of impedance monitoring relies on use of symptom correlation measures (SI, SSI or SAP). The therapeutic implications of an abnormal impedance test are unproven at this time.

Bile acid reflux testing may be useful:

- Evaluation of patients with persistent typical reflux symptoms in spite of demonstrated normalization of distal esophageal acid exposure by pH study. Impedance monitoring may obviate the need for bile acid reflux testing under such circumstances.
- Bile acid reflux testing equipment currently has very limited commercial availability.

In 2005, the 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). There have been no updates to these guidelines since 2005.

American Society for Gastrointestinal Endoscopy (ASGE): In 2005, the 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). There have been no updates to these guidelines since 2005.

American Gastroenterological Association (AGA): In 2008, the AGA issued a medical position statement on the management of GERD (Kahrilas, et al., 2008). In the development of this medical position statement, 12 broad questions pertinent to diagnostic and management strategies for patients with GERD were developed by interaction among the authors of the technical review, representatives from the AGA Institute Council, and the AGA Institute Clinical Practice and Quality Management Committee. The questions were designed to encapsulate the major management issues encountered in patients with GERD in current clinical practice. The resultant conclusions were based on the best available evidence or, in the absence of quality evidence, expert opinion. The strength of these conclusions was weighed using US Preventive Services Task Force (USPSTF) grades. There have been no updates to these guidelines since 2008.

The recommendations for the question of what is the role and priority of diagnostic tests (endoscopy with or without biopsy, esophageal manometry, ambulatory pH monitoring, impedance-pH monitoring) in the evaluation of patients with suspected esophageal GERD syndromes states:

Grade B: recommended with fair evidence that it improves important outcomes:

- When ambulatory impedance-pH, catheter pH, or wireless pH monitoring (PPI therapy withheld for 7 days) to evaluate patients with a suspected esophageal GERD syndrome who have not responded to an empirical trial of PPI therapy, have normal findings on endoscopy, and have no major abnormality on manometry. Wireless pH monitoring has superior sensitivity to catheter studies for detecting pathological esophageal acid exposure because of the extended period of recording (48 hours) and has also shown superior recording accuracy compared with some catheter designs.

Grade Insuff: no recommendation, insufficient evidence to recommend for or against:

- Combined impedance-pH, catheter pH, or wireless pH monitoring studies to distinguish hypersensitivity syndromes from functional syndromes, the distinction being that in hypersensitivity syndromes

symptoms are attributable to reflux events, whereas in functional syndromes they are not. Combined impedance-pH, catheter pH, or wireless pH esophageal monitoring studies performed while taking PPIs.

In 1996, the American Gastroenterological Association (AGA) issued guidelines on the use of esophageal pH recording. The guidelines do not specifically address the use of wireless esophageal pH monitoring. There have been no updates to these guidelines since 1996.

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

Professional society guidelines refer to wireless esophageal potential of hydrogen (pH) monitoring as a technology that may alter the management of gastrointestinal reflux disease (GERD). Although no large, prospective, controlled trials with reported long-term health outcomes have been performed to compare the diagnostic and therapeutic utility of wireless pH monitoring with conventional transnasal pH monitoring, wireless esophageal pH monitoring has become an alternative to a subset of patients who cannot tolerate conventional catheter-based esophageal pH monitoring systems. The reported major advantages of wireless esophageal pH monitoring to conventional catheter-based esophageal monitoring is 48 hours of monitoring and patient tolerability.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
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91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation
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ICD-9-CM Diagnosis Codes	Description
150.0-150.5	Malignant neoplasm of esophagus
472.1	Chronic pharyngitis
476.0	Chronic laryngitis
476.1	Chronic Laryngotracheitis
493.90	Asthma, unspecified
507.0	Pneumonitis due to inhalation of food or vomitus
530.20	Ulcer of esophagus without bleeding
530.21	Ulcer of esophagus with bleeding
530.3	Stricture and stenosis of esophagus
530.81	Esophageal reflux
535.10	Atrophic gastritis, without mention of hemorrhage
535.40	Other specified gastritis, without mention of hemorrhage
535.50	Unspecified gastritis, without mention of hemorrhage
538.85	Barrett's esophagus
784.42	Dysphonia
786.2	Cough
786.50	Chest pain, unspecified
786.59	Chest Pain, other
787.01	Nausea with vomiting
787.02	Nausea alone
787.03	Vomiting alone
787.1	Heartburn
787.20	Dysphagia, unspecified

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
530.10	Esophagitis, unspecified
530.11	Reflux esophagitis
530.19	Other esophagitis

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

References

1. Ahlawat 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.
3. Bechtold ML, Holly JS, Thaler K, Marshall JB. Bravo (wireless) ambulatory esophageal pH monitoring: how do day 1 and day 2 results compare? World J Gastroenterol. 2007 Aug 14;13(30):4091-5.

4. Blue Cross and Blue Shield Technology Assessment. Special report: wireless esophageal pH monitoring. Assessment program. Volume 21. May 2006. Accessed February 17, 2011. Available at URL address: <http://www.bcbs.com/blueresources/tec/>
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. 6th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2009. Ch 61.
6. Centers for Medicare & Medicaid Services. NCD for 24-Hour Ambulatory Esophageal pH Monitoring (100.3). Effective Date June 11, 1985. Accessed February 17, 2011. 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. September 19, 2003. Accessed February 17, 2011. Available at URL address: <http://www.cignagovernmentservices.com/partb/pubs/news/2003/0603/COPE579.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. 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.
12. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2011 Jan 31. Telemetric Capsule-based Esophageal pH Monitoring to Aid in Diagnosis of Gastroesophageal Reflux Disease. 2011 Jan 31. Available at URL address: <http://www.ecri.org>.
13. Given[®] Imaging. Bravo system pH monitoring. Accessed February 17, 2011. Available at URL address: <http://www.givenimaging.com/en-us2/HealthCareProfessionals/Pages/pageHCP.aspx>
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. Grigolon A, Bravi I, Cantù P, Conte D, Penagini R. Wireless pH monitoring: better tolerability and lower impact on daily habits. *Dig Liver Dis.* 2007 Aug;39(8):720-4.
16. Hirano I, Richter JE; Practice Parameters Committee of the American College of Gastroenterology. ACG practice guidelines: esophageal reflux testing. *Am J Gastroenterol.* 2007 Mar;102(3):668-85.
17. 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 February 17, 2011. Available at URL address: <http://www.effectivehealthcare.ahrq.gov/index.cfm/guides-for-patients-and-consumers/>
18. Iqbal A, Lee YK, Vitamvas M, Oleynikov D. 48-Hour pH monitoring increases the risk of false positive studies when the capsule is prematurely passed. *J Gastrointest Surg.* 2007 May;11(5):638-41.

19. Kahrilas PJ, Shaheen NJ, Vaezi MF, Hiltz SW, Black E, Modlin IM, et al. American Gastroenterological Association. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008 Oct;135(4):1383-1391, 1391.e1-5.
20. Kahrilas PJ, Shaheen NJ, Vaezi MF; American Gastroenterological Association Institute; Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute technical review on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008 Oct;135(4):1392-1413, 1413.e1-5. Epub 2008 Sep 16.
21. Lawrence BL, Taylor D. Esophageal pH monitoring goes wireless. *Nursing*. 2007 Oct;37(10):26-7.
22. 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.
23. National Institute for Health and Clinical Excellence (NICE). Catheterless esophageal pH monitoring. July 2006. Accessed February 17, 2011. Available at URL address: <http://www.nice.org.uk/page.aspx?o=ipg187guidance>
24. [No authors listed]. Special report: wireless esophageal pH monitoring. *Technol Eval Cent Asses Program Exec Summ*. 2006 May;21(2):1-2. Accessed February 17, 2011. Available at URL address: <http://www.bcbs.com/betterknowledge/tec/>
25. North American Society for Pediatric Gastroenterology and Nutrition. Pediatric GE Reflux Clinical Practice Guidelines. 2001. Accessed February 17, 2011. Available at URL address: <http://www.naspghan.org/sub/positionpapers.asp>
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*. 2005a Dec;54(12):1687-92.
27. Pandolfino JE, Kahrilas PJ. Prolonged pH monitoring: Bravo capsule. *Gastrointest Endosc Clin N Am*. 2005b 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, Friedenberg FK. Gastroesophageal reflux disease. In: Feldman M, Friedman LS, Brandt LJ, editors. *Sleisenger and Fordtran's Gastrointestinal and liver disease*. 9th ed. Philadelphia, PA: W.B. Saunders Co; 2010. Ch 43; pg 717.
32. Roberts JR, Castell DO. Gastroesophageal reflux disease. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy 2011*. 1st ed. St. Louis, MO: W.B. Saunders Co.; 2010. Section 7.
33. Scarpulla G, Camilleri S, Galante P, Manganaro M, Fox M. The impact of prolonged pH measurements on the diagnosis of gastroesophageal reflux disease: 4-day wireless pH studies. *Am J Gastroenterol*. 2007 Dec;102(12):2642-7.
34. 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.

35. Tseng D, Rizvi AZ, Fennerty MB, Jobe BA, Diggs BS, Sheppard BC, et al. 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.
36. 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.
37. 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). K002028. 2000 Sep. Accessed February 18, 2011. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>
38. Vollweiler JF, Vaezi MF. The esophagus: anatomy, physiology and diseases. Esophageal testing. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR., editors. *Otolaryngology Head and Neck Surgery.* 5th ed. Philadelphia, PA; Mosby; 2010. Ch 72.
39. Wenner J, Johansson J, Johnsson F, Oberg S. Optimal thresholds and discriminatory power of 48-h wireless esophageal pH monitoring in the diagnosis of GERD. *Am J Gastroenterol.* 2007b Sep;102(9):1862-9.
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.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0329	Wireless Esophageal pH Monitoring System (Bravo™)
Great-West Healthcare	8/23/2007	05.314.02	Esophageal pH Monitoring, Wireless (Bravo)

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