



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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Endoscopic Anti-Reflux Procedures
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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers wireless esophageal pH monitoring (e.g., Bravo™ pH Monitoring System [Medtronic, Inc., Shoreview, MN]) as medically necessary for ANY of the following:

- to document abnormal esophageal acid exposure in an endoscopy-negative individual being considered for surgical antireflux repair
- to evaluate endoscopy-negative individuals with typical reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy
- to document adequacy of PPI therapy in esophageal acid control in individuals with complications of reflux disease that include Barrett's esophagus
- to evaluate endoscopy-negative individuals with atypical reflux symptoms that are refractory to twice per day PPI therapy
- to evaluate individuals after antireflux surgery who are suspected to have ongoing abnormal reflux and have not responded to empiric trials of PPI therapy

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

- to detect or verify reflux esophagitis
- to evaluate 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 (Tseng, et al., 2005; Pandolfino, et al., 2005b, Richter, 2003).

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, 2008; 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 (Medtronic, 2008). 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 (Medtronic, 2008).

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.

Literature Review

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

In 2007, the American College of Gastroenterology (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 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 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. There have been no updates to these guidelines since 2005 (DeVault and Castell, 2005).

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. There have been no updates to these guidelines since 2005 (Chotiprashidi, et al., 2005).

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). Evidence in the published, peer-reviewed scientific literature suggests that wireless esophageal pH monitoring can provide clinically useful data for some patients; however, no large, prospective, controlled trials have been performed to compare wireless pH monitoring with conventional, transnasal pH monitoring and to determine the relative sensitivity and specificity of these two techniques. Wireless esophageal pH monitoring offers a safe alternative to a subset of patients who cannot tolerate conventional catheter-based esophageal pH monitoring systems.

Coding/Billing Information

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

Covered when medically necessary:

CPT ^{®*} Codes	Description
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

ICD-9-CM Diagnosis Codes	Description
530.81	Esophageal reflux

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
530.11	Reflux esophagitis

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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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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