POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, catheter-based esophageal pH monitoring for adults and adolescents, or for children who are able to report symptoms, has been medically proven to be effective and is considered medically appropriate for any of the following indications:
   A. Documentation of abnormal acid exposure in endoscopy-negative patients who are being considered for surgical antireflux repair;
   B. Evaluation of patients after antireflux surgery who are suspected to have ongoing abnormal reflux;
   C. Evaluation of patients with normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy after a 4-week trial;
   D. Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and a 4-week trial of PPI therapy;
   E. Evaluation of suspected otolaryngologic manifestations of GERD (e.g., laryngitis, pharyngitis, chronic cough) that have failed to respond to 4 weeks of PPI therapy; or
   F. Evaluation of concomitant GERD in an adult-onset, nonallergic asthmatic suspected of having reflux-induced asthma.

II. Based upon our criteria and assessment of peer-reviewed literature, catheter-based esophageal pH monitoring has been medically proven effective and is considered medically appropriate in infants or children who are unable to report or describe symptoms of reflux for any of the following indications:
   A. Unexplained apnea;
   B. Bradycardia;
   C. Refractory coughing, wheezing or stridor;
   D. Recurrent choking or aspiration;
   E. Persistent or recurrent laryngitis; or
   F. Recurrent pneumonia.

III. Based upon our criteria and assessment of peer-reviewed literature, a catheter-free or wireless esophageal pH monitoring system (e.g., BRAVOTM system by Medtronic) is considered medically appropriate as an alternative to the conventional, catheter-based method for those patients who meet the indications for the catheter-based monitoring.

DESCRIPTION:

Recurring reflux, or regurgitation of the stomach contents into the esophagus causes gastroesophageal reflux disease (GERD). GERD can lead to complications such as esophagitis, esophageal erosion, stricture and Barrett’s esophagus (a premalignant condition). GERD is usually diagnosed by clinical history and is treated empirically with a trial of medical management. Esophageal pH monitoring is an important diagnostic test in the evaluation of those patients with GERD who require further evaluation if an adequate response to acid suppression therapy has not been achieved. Esophageal pH monitoring provides quantitative data on both esophageal acid exposure and the correlation between patient symptoms and reflux events.
Conventional esophageal pH monitoring uses a tube or catheter with a pH electrode attached to its tip, which is passed orally/nasally to 5 cm above the upper margin of the lower esophageal sphincter. The catheter is then connected to a data recorder, which is attached to a waist belt or shoulder strap. The number of reflux events and the esophageal acid exposure time associated with each event is recorded and an event marker is activated in response to symptoms, meals and changes in body position. Additionally, patients are asked to keep a diary of symptoms and activities. The data recorded is compared with the diary information after the 24-hour monitoring period.

A catheter-free or wireless diagnostic system for measuring esophageal pH levels has recently been developed. The wireless system consists of a pH sensor that is inserted either orally or nasally and temporarily attached to the esophageal wall with a pin mechanism after an endoscopic procedure for proper anatomical placement. Once activated, the sensor then monitors and transmits esophageal pH levels to an outside receiver worn by the patient for approximately 48 hours. As with the catheter-based method, the patient keeps a diary of symptoms and activities, which can be correlated with the data from the receiver. The sensor is spontaneously released from the esophageal wall and passes through the digestive tract within a few days.

The wireless system has been marketed as a replacement for the catheter-based system. Catheter-based pH monitoring can be uncomfortable for some patients and some patients may restrict their activities and diet while the catheter is in place, leading to potentially false negative studies. The wireless system has been proposed to be more comfortable and less conspicuous for patient, thus allowing for more natural patient activities. The wireless system also allows a longer monitoring period of approximately 48 hours.

RATIONALE:

Esophageal pH monitoring using the catheter-based method: There are numerous catheter-based pH monitoring systems with FDA clearance. 24-hour, catheter-based esophageal monitoring is a well-established technology, primarily used in patients with GERD who have not responded symptomatically to a program of medical therapy, or in patients with refractory extraesophageal symptoms. The American Gastroenterological Association has published guidelines for the clinical use of esophageal pH recording. The sensitivity of the test is close to 96% with a specificity of 85-100%. Ambulatory 24-hour esophageal pH monitoring quantifies the degree of reflux in a near physiological setting and relates the patient’s symptoms and activities to the occurrence of acid reflux events.

Esophageal pH monitoring using the wireless method: BRAVO™ pH Monitoring System by Medtronic, a catheter-free or wireless system, received FDA 510 (k) clearance in September 2002. A recent comparison study between the 2 types of devices was conducted using 25 healthy volunteers (Pandolfino et al. 2005). All patients in the study underwent simultaneous pH monitoring using both devices. Of the 25 patients, data could not be analyzed on 7 patients- 6 patients experienced capsule displacement and 1 patient could not tolerate the catheter. Regarding available outcome data, the recorded acid exposure was similar between the 2 systems. Wong, et al. (2005) conducted a randomized study to compare the tolerability of the wireless pH capsule versus the traditional pH probe. 25 patients were randomized to each group. Though patients in the wireless capsule group experienced less nose, throat pain/discomfort then the traditional probe group, the wireless group had more chest and esophageal discomfort during the test. A case series by 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.

Recent studies (SB des Varannes et al. 2005, D Tseng, et al. 2005, JE Pandolfino, et al. 2005, and YM Bhat et al. 2006) demonstrate that the wireless procedure is successfully performed and produces successful measurement of esophageal acid in a high proportion (90%) of cases. Overall, it is more comfortable than traditional wired monitoring. Measurements correlate fairly closely to wired monitoring after adjusting test thresholds; however, because of the lack of an established
gold standard, even when the two devices are discrepant, it cannot be determined which device is “correct.” Also, different studies have produced different cutoff values for a normal test. More data are needed to establish appropriate diagnostic thresholds. No studies establish that wireless monitoring is superior to wired monitoring in reaching a GERD diagnosis or optimally managing a patient.

**CODES:**

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<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.</td>
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CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**

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<td>Upper gastroesophageal endoscopy</td>
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<td>91034</td>
<td>Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation</td>
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<tr>
<td>91035</td>
<td>Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation</td>
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**HCPCS:**

No specific codes

**ICD9:**

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<td>493.00-90</td>
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<td>507.0</td>
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<td>770.81-89</td>
<td>Respiratory problems, including apnea, originating in the perinatal period (code range)</td>
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**ICD10:**

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<td>R00.1</td>
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Proprietary Information of Excellus Health Plan, Inc.
REFERENCES:


| SUBJECT: ESOPHAGEAL PH MONITORING | EFFECTIVE DATE: 12/15/05 |
| POLICY NUMBER: 2.01.44 | REVISED DATE: 12/21/06, 10/18/07, 09/18/08, 09/17/09, 08/19/10 |
| CATEGORY: Technology Assessment | ARCHIVED DATE: 07/21/11 |
| | EDITED DATE: 07/19/12, 07/18/13, 07/17/14, 07/16/15, 07/21/16 |
| | PAGE: 5 OF: 6 |


*Proprietary Information of Excellus Health Plan, Inc.*
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Proprietary Information of Excellus Health Plan, Inc.


Wireless pH recording immediately above the squamocolumnar junction improves the diagnostic performance of esophageal pH studies. Am J Gastroenterol 2008 Dec;103(12):2977-85.


KEY WORDS:
Wireless, Bravo

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for 24-hour ambulatory esophageal monitoring. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=108&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAABAAAAAA