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Subject:	Esophageal pH Monitoring	Page:	1 of 9

Last Review Status/Date: March 2017

Esophageal pH Monitoring

Description

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of 1 to several days. Impedance pH monitoring measures electrical impedance in the esophagus to evaluate reflux episodes concurrent with changes in pH. These tests are used for certain clinical indications in the evaluation of gastroesophageal reflux disease (GERD).

Background

Acid reflux is the cause of heartburn and acid regurgitation esophagitis, which can lead to esophageal stricture. Acid reflux may also be the cause or a contributing factor in some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis, subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia.

GERD is most commonly diagnosed by clinical evaluation and treated empirically with a trial of medical management. For patients who do not respond appropriately to medications, or who have recurrent chronic symptoms, endoscopy is indicated to confirm the diagnosis and assess the severity of reflux esophagitis. In some patients, endoscopy is non-diagnostic, or results are discordant with the clinical evaluation. In these cases, further diagnostic testing may be of benefit.

Esophageal monitoring is done through the use of a tube with a pH electrode attached to its tip, which is then passed to almost exactly 5 cm above the upper margin of the lower esophageal sphincter. The electrode is attached to a data recorder worn on a waist belt or shoulder strap. Every instance of acid reflux, as well as its duration and pH, is recorded, indicating gastric acid reflux over a 24-hour period. Using endoscopic or manometric guidance, the capsule is temporarily implanted in the esophageal mucosa using a clip. The capsule records pH levels for up to 96 hours and transmits them via radiofrequency telemetry to a receiver worn in the patient's belt. Data from the recorder are uploaded to a computer for analysis by a nurse or doctor.

Another technology closely related to pH monitoring is impedance-pH monitoring, which incorporates pH monitoring with measurements of impedance, a method of measuring reflux of liquid or gas of any pH. Multiple electrodes are placed along the length of the esophageal catheter. The impedance pattern detected can determine the direction of flow and the substance (liquid or gas). Impedance monitoring is able to identify reflux events in which the liquid is only slightly acidic or nonacidic.

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Regulatory Status

Esophageal pH electrodes are U.S. Food and Drug Administration (FDA) 510(k) exempt Class I devices. A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System, Medtronic) has been cleared for marketing by the FDA 510(k) (September 2000) process for the purpose of gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.

A number of wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared through the 510(k) process. Some examples are the Bravo pH Monitoring System (Given Imaging), the Sandhill Scientific PediaTec™ pH Probe (Sandhill Scientific), the ORION II Ambulatory pH Recorder (MMS, Medical Measurement Systems) and the TRIP CIC Catheter (Tonometrics). FDA product code: FFT.

Policy

**This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Esophageal pH monitoring using a wireless or catheter-based system may be considered **medically necessary** for the following clinical indications in adults and children or adolescents able to report symptoms.*

- Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical anti-reflux repair
- Evaluation of patients after anti-reflux surgery who are suspected of having ongoing abnormal reflux
- Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy
- Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a 1-month trial of PPI therapy
- Evaluation of suspected otolaryngologic manifestations of GERD (ie, laryngitis, pharyngitis, chronic cough) that have failed to respond to at least 4 weeks of PPI therapy
- Evaluation of concomitant GERD in an adult-onset, non-allergic asthmatic suspected of having reflux-induced asthma

24-hour catheter-based esophageal pH monitoring may be considered **medically necessary** in infants or children who are unable to report or describe symptoms of reflux with:

- unexplained apnea;
- bradycardia;
- refractory coughing or wheezing, stridor, or recurrent choking (aspiration);
- persistent or recurrent laryngitis; and
- recurrent pneumonia

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Catheter-based impedance-pH monitoring in patients refractory to proton pump inhibitor therapy may be considered **medically necessary**.

* Esophageal pH monitoring systems should be used in accordance with U.S. Food and Drug Administration–approved indications and age ranges.

Policy Guidelines

Esophageal pH monitoring systems should be used in accordance with FDA-approved indications and age ranges.

Rationale

No new evidence was identified in the latest review that would change the conclusions of this Policy. The following is a summary of the key literature.

Esophageal pH monitoring using catheter-based systems

Esophageal pH monitoring for 24 hours using catheter-based systems has been an established technology, primarily used in patients with gastroesophageal reflux disease (GERD) that has not responded symptomatically to a program of medical therapy (including proton pump inhibitors [PPIs] or in patients with refractory extra-esophageal symptoms). Although it is an established technology, aspects of its use as a diagnostic test for GERD are problematic and thus make it difficult to determine its utility, as well as the utility of potential alternative tests.

There is no independent reference standard for GERD for specific populations. Traditional pH monitoring has been evaluated in patients with endoscopically diagnosed GERD, where it has been shown to be positive 77% to 100% of the time. (1) However, in clinically defined but endoscopically negative patients, the test is positive from 0% to 71% of the time. In normal control populations, traditional pH monitoring is positive in 0% to 15% of subjects. Thus the test is imperfectly sensitive and specific in patients with known presence or absence of disease. The state of this evidence regarding the diagnostic capability of catheter-based pH monitoring led the authors of this technical review "...to conclude that ambulatory pH studies quantify esophageal acid exposure but that this has an imperfect correlation with reflux-related symptoms, esophageal sensitivity, or response to acid suppressive therapy." (1)

Without a reference standard for GERD, it is difficult to compare the diagnostic test performance of different types of tests. It is possible to determine the degree to which 2 tests correlate with each other, but difficult to determine if 1 test is better.

Wireless pH Monitoring

Several observations of relevance to this Policy are based on a 2006 TEC Special Report on wireless esophageal pH monitoring. (2) Six case series compiled in the report demonstrated success rates over 90% in achieving a 48-hour pH study. Two studies that surveyed patients who received wireless pH monitoring and patients who received traditional catheter monitoring showed less discomfort, less

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disruption of daily activities, and higher overall satisfaction with the experience. Studies that evaluated test positivity in clinically diagnosed GERD cases and normal controls showed similar results as have been reported in such patients using traditional pH monitoring. Studies that directly compared the performance of traditional catheter and wireless pH monitoring in the same patients showed fairly close correlation between the 2 types of studies after correcting for calibration differences. However, the ideal cut-point for test positivity was different for the tests.

Some studies attempted to support an argument that the longer monitoring time that the wireless monitor allows results in superior test performance. However, without a reference standard, or showing superior patient outcomes based on the longer test, such an argument cannot be made. The longer monitoring period usually results in a larger proportion of tests that are classified as positive, depending on the method of determining a positive test. Prakash and Clouse compared the diagnostic yield for a single day of monitoring compared to the complete 2 days of monitoring. (3) They reported that the second day of recording time increased the proportion of subjects with symptoms by 6.8%. However, this study had several methodologic flaws. Ideally, a study that compares the diagnostic performance of an additional day of monitoring would require an independent reference standard or demonstration of improved patient outcomes when managing patients with a 1-day versus a 2-day study. In this study, the 2-day study was essentially considered the “reference test,” and there was no discussion of how the second day of monitoring was used to improve patient management in this heterogeneous group of patients. In addition, in their statistical analysis, the authors eliminated patients who did not report any symptoms during the testing period, thus deflating the denominator and inflating the yield of the additional day of testing. Finally, the 1-day test was essentially a component of the 2-day test, and thus the 2 monitoring periods were not independent, further limiting any comparison between them. It should not be presumed that the greater number of positive tests produced by a longer duration of test is evidence of a superior test.

Studies published since the 2006 TEC Special Report was prepared essentially show similar types of findings regarding the correlation of wireless pH monitoring and standard catheter monitoring. Wenner et al, in a study of 64 patients with GERD and 50 asymptomatic controls, showed a sensitivity of 59% to 65%, when setting the specificity to 90% to 95%. (4) This was noted to be worse than other studies of traditional pH monitoring, but the patient population may have had less severe disease. A study by Schneider et al showed similar diagnostic performance of wireless and traditional pH monitoring. (5) Hakanson et al evaluated simultaneous wireless and traditional pH testing in 92 patients. (6) Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The 2 techniques were correlated ($r^2=0.66$); however, the range between limits of agreement was wide. The techniques were concordant regarding the final diagnosis 82.1% of the time.

Additional studies replicate findings that a longer period of monitoring increases the proportion of positive tests. Scarpulla et al attempted 96-hour monitoring in 83 patients. (7) Monitoring for the full 96 hours was successful in 41% of patients. In these patients, the proportion showing some degree of pathologic acid exposure increased as the time of monitoring increased. Garrean et al studied the use of 96-hour pH testing where during the first 2 days of monitoring, the patients were off therapy, and during the second 2 days, the patients were prescribed PPIs. (8) As expected, during the second and third days, fewer patients showed reflux symptoms. It is difficult to determine from the analysis of data how such a testing protocol improves the diagnosis of GERD. Grigolon et al showed that in 51 patients receiving prolonged monitoring, the 96-hour test reduced the number of indeterminate tests from 11 to

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5. (9) In this particular study, comparison of outcomes of patients who received wireless monitoring and a matched control group of patients who received traditional catheter monitoring showed similar outcome and satisfaction.

Impedance-pH Testing

Evidence on the use of impedance-pH testing suffers from similar issues as the evaluation of wireless pH testing: lack of a reference standard, and lack of evidence that shows improved patient outcomes. Many studies use the argument that an increase in positive tests, or diagnostic yield as it is called, by itself is evidence that supports the use of the test. However, the increase in positive tests, if it is reflective of a potentially increased sensitivity, may be accompanied by a decrease in specificity. The net effect on patient management and patient outcomes is not certain.

Several studies have demonstrated a higher yield of positive tests when using impedance-pH testing and identifying reflux events that are non- or only weakly acidic (and thus would not be detected using pH testing alone). (10-12) Bajbouj et al studied 41 patients with atypical GERD symptoms with numerous tests. (10) The test that produced the highest number of positive findings was impedance-pH testing. Bredenoord et al did a similar study in 48 patients. (11) A higher proportion of subjects had positive tests when using impedance-pH data than when using pH data alone (77% vs 67%, respectively). A study by Mainie et al showed similar findings. (12)

Studies have examined the issue of performing impedance-pH testing while the patient is currently on acid suppression therapy. Vela et al demonstrated that during acid suppressive therapy, the total number of reflux episodes is similar, but fewer episodes of acidic reflux occur. (13)

Although impedance-pH testing produces a higher number of positive tests, particularly when compared with traditional or wired pH testing in the setting of concurrent acid suppressive therapy, there is not sufficient evidence that these test results are more accurate, nor is there a clear link to improved patient outcomes when using impedance-pH testing compared with other methods of measuring pH.

Practice Guidelines and Position Statements

American College of Gastroenterology

The American College of Gastroenterology (ACG) released practice guidelines on esophageal reflux testing in 2007. (14) The literature up to 2006 was reviewed. Although the literature on wireless pH testing was extensively reviewed, the recommendations for testing made no distinction between wireless and traditional pH monitoring. An indirect endorsement of wireless monitoring might be inferred from a statement that says that a 48-hour study would produce a greater diagnostic yield from a symptom-association test. Symptom-association tests require statistical testing of the data, and a 48-hour test produces more data points. However, apparently these statistical correlation tests are not perfect, as the guidelines state that such measures “do not ensure a response to either medical or surgical antireflux therapies.” No studies were cited in these guidelines that indicate superior outcomes for patients for treatment guided by wireless pH testing versus traditional pH testing. The major advantage for the wireless system cited was patient tolerability.

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Impedance-pH monitoring was cited as “may be useful” (a lower category of recommendation than for pH monitoring) for evaluation of patients with insufficient response to medical therapy in whom documentation of nonacid reflux would alter clinical management. It was suggested that impedance monitoring has a greater yield for findings than pH monitoring when performed on PPI therapy. The last statement of the guideline states that implications of an abnormal impedance test are unproven at this time.

In 2013, ACG published guidelines on the diagnosis and management of gastroesophageal reflux disease. (15) The guidelines indicate “ambulatory esophageal reflux monitoring is indicated before consideration of endoscopic or surgical therapy in patients with non-erosive disease, as part of the evaluation of patients’ refractory to PPI therapy, and in situations when the diagnosis of GERD is in question.” This was a strong recommendation based on a low level of evidence. The guidelines note there is limited evidence and lack of clear consensus on how testing should be performed, eg, catheter-based pH, wireless pH, or impedance-pH, for refractory GERD.

American Gastroenterological Association

The American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD in 2008. (16) Ambulatory impedance-pH, catheter pH, and wireless pH monitoring were all supported as methods to evaluate patients with suspected GERD with otherwise normal endoscopy and no response to PPI therapy. The guideline is classified as a “Grade B” recommendation, denoting fair evidence that the practice improves health outcomes. The guideline additionally states that the wireless pH monitor has superior sensitivity to catheter pH monitoring because of the extended period of recording.

However, as noted previously, an increase in positive tests has been documented in other reports as producing both increased sensitivity and decreased specificity relative to the reference standard used in the particular study. Thus, taking into account both characteristics of diagnostic performance, it is unknown as to whether patient outcomes are improved.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) released technology appraisal guidance on catheterless esophageal pH monitoring in July 2006. (17) This guidance indicates catheterless esophageal pH monitoring appears to be safe and effective and is commonly indicated for GERD symptoms refractory to proton pump inhibitors and for GERD symptom recurrence after anti-reflux surgery.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Summary of Evidence

For individuals who have gastroesophageal reflux disease (GERD) who receive catheter-based pH monitoring, the evidence includes various cross-sectional studies in different populations evaluating

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test performance. Relevant outcomes include test accuracy and validity, symptoms, and functional outcomes. Positive pH monitoring tests correlate with endoscopically defined GERD and with GERD symptoms, but because there is no reference standard for clinical GERD, diagnostic characteristics cannot be determined. There are no studies of clinical utility showing improved outcomes, and the indirect chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

For individuals who have GERD who receive wireless pH monitoring, the evidence includes various cross-sectional studies in different populations evaluating test performance and diagnostic yield. Relevant outcomes include test accuracy and validity, symptoms, and functional outcomes. Positive wireless pH monitoring tests correlate with endoscopically defined GERD and with GERD symptoms, but because there is no reference standard for clinical GERD, diagnostic characteristics cannot be determined. Some studies have shown higher positive test rates with prolonged wireless monitoring compared to catheter-based pH monitoring, but the effect of this finding on patient outcomes is uncertain. There are no studies of clinical utility showing improved outcomes, and the indirect chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

For individuals who have GERD who receive impedance pH testing, the evidence includes various cross-sectional studies in different populations evaluating test performance and diagnostic yield. Relevant outcomes include test accuracy and validity, symptoms, and functional outcomes. Positive impedance pH tests correlate with endoscopically defined GERD and with GERD symptoms, but because there is no reference standard for clinical GERD, diagnostic characteristics cannot be determined. Some studies have shown higher positive test rates with impedance pH testing compared to pH testing alone, but the effect of this finding on patient outcomes is uncertain. There are no studies of clinical utility showing improved outcomes, and the indirect chain of evidence supporting utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

Medicare National Coverage

There is no national coverage determination (NCD).

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Policy History

Date	Action	Reason
September 2011	New Policy	

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December 2012	Update Policy	Policy updated with literature through August 2012, reference 17-18 added. Added wireless pH monitoring to the first medically necessary to the first medically necessary policy statement, third and fourth policy statements on 48-to 96- hour, catheter-free, wireless esophageal monitoring deleted. Added monitoring must be done in accordance with FDA approved indications and age ranges to policy statement. Updated policy statement for catheter based impedance-pH monitoring to - may be considered medically necessary in patients with manifestations of GERD with inconclusive pH monitoring test results.
September 2013	Update Policy	Policy updated with literature search, References 10-14 added. The policy statement on impedance monitoring was changed to: Catheter-based impedance-pH monitoring in patients refractory to proton pump inhibitor therapy may be considered medically necessary .
September 2014	Update Policy	Policy updated with literature search; reference 15 added. Policy statements unchanged.
September 2015	Update Policy	Policy updated with literature review; no new references added. Policy statements unchanged.
Mardh 2017	Update Policy	Policy updated with literature review; no references added. Policy statements unchanged.

Keywords

Acid Reflux Test
 Bravo pH Monitoring System
 Esophageal pH Monitoring
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 Monitoring, Esophageal pH
 pH Monitoring, Esophageal

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 17, 2017 and is effective April 15, 2017.

Signature on File

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