



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Esophageal pH Monitoring

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Last Review: 11/2013

Origination: 11/2003

Next Review: 11/2014

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for esophageal pH Monitoring when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Esophageal pH monitoring 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 to have ongoing abnormal reflux.
- Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy.
- Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a one month trial of proton pump inhibitor therapy.
- Evaluation of suspected otolaryngologic manifestations of GERD (i.e., laryngitis, pharyngitis, chronic cough) that have failed to respond to at least 4 weeks of proton pump inhibitor therapy.
- Evaluation of concomitant GERD in an adult-onset, nonallergic 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.

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

When Policy Topic is not covered

Esophageal pH monitoring is considered not medically necessary when the criteria above are not met.

Catheter-based impedance-pH monitoring is considered **not medically necessary**.

Considerations

Manometry, when used for pH tip placement, should be considered part of the pH recording.

Description of Procedure or Service

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of one to several days. These devices may aid in the diagnosis of gastroesophageal reflux disease (GERD) in patients who have an uncertain diagnosis after clinical evaluation and endoscopy.

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.

Gastroesophageal reflux disease (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 (LES). The electrode is attached to a data logger 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. 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) process for the purpose of "gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age." 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 non-acidic.

Rationale

This policy was originally created in 1996 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed through April 2013. The following is a summary of the key literature to date.

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 [PPI]) 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 certain clinically relevant populations. Traditional pH monitoring has been evaluated in patients with endoscopically diagnosed GERD, where it has been shown to be positive 77-100% of the time. (1) However, in clinically defined but endoscopically negative patients, the test is positive from 0-71% of the time. In normal control populations, traditional pH monitoring is positive in 0-15% 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 diagnostic test performance between different types of tests. It is possible to determine whether 2 tests correspond close enough that they might be considered equivalent tests. Use of one test versus another may result in better patient outcomes, if despite being an imperfect test, differences in patient management based on the test results result in overall improved patient outcomes. However, this type of argument would require rigorous studies that follow patients beyond test outcome and are organized and analyzed such that a valid inference of improved outcome due to the use of the test can be made.

Wireless pH monitoring

A 2006 TEC Special Report on wireless esophageal monitoring made several observations regarding wireless pH monitoring. (2) Six case series demonstrated high success rates in successfully performing the procedure, with 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 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 directly comparing the performance between traditional catheter and wireless pH monitoring in the same patients showed fairly close correlation between the two types of studies after correcting for calibration differences. The ideal cut-point for test positivity was different for the two types of 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. As reviewed in the 2006 TEC Special Report, Prakash and Clouse compared the diagnostic yield for a single day of monitoring compared to the complete 2 days of monitoring. (3) The authors reported that the second day of recording time increased the number of subjects recording symptoms by 6.8%. However, this study had several methodologic flaws. Ideally, a study comparing 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 essentially show similar types of findings regarding the correlation of wireless pH monitoring and standard catheter monitoring. Wenner and colleagues, in another study of 64 patients with GERD and 50 asymptomatic controls, showed a sensitivity of 59–65%, when setting the specificity to 90–95%. (4) This was noted to be worse than other studies of traditional pH monitoring, but the patient population may have had less severe disease. The 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 -squared=0.66); however, the range between limits of agreement was wide. The 2 techniques were concordant regarding the final diagnosis 82.1% of the time.

Additional studies since the 2006 TEC Special Report also repeat the 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 2 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 5. (9) In this particular study, comparison of outcomes of patients receiving wireless monitoring and a matched control group of patients receiving traditional catheter monitoring showed similar outcome and satisfaction.

Impedance-pH testing

Evidence supporting 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 showing 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 there are fewer episodes of acidic reflux. (13)

Although impedance-pH testing produces a higher number of positive tests, particularly when compared to 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 to other methods of measuring pH. Thus, this testing is considered not medically necessary.

Ongoing Clinical Trials

A May 2013 search of online site ClinicalTrials.gov identified several active studies using esophageal pH and impedance monitoring as an evaluation tool for research of various treatments such as pharmaceutical products for GERD. However, no active studies on the diagnostic and clinical utility of esophageal pH and impedance monitoring were identified.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review for 2010. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The input was mixed. A majority of the reviewers indicated that the wireless device was more comfortable and allowed patients to have more varied activities during the recording. One reviewer cited problems with availability of the catheter-based systems. Most agreed that a linkage between wireless monitoring and improved health outcome had not been demonstrated.

Summary

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of one to several days. These devices may aid in the diagnosis of gastroesophageal reflux disease (GERD) in patients who have an uncertain diagnosis after clinical evaluation and endoscopy. Therefore, the use of wired or wireless esophageal pH monitoring may be considered medically necessary in the patient meeting the above criteria.

Given the lack of a gold standard, evidence supporting the use of impedance-pH testing is lacking. While impedance-pH testing may increase positive tests or diagnostic yield, the potentially increased sensitivity may be accompanied by a decrease in specificity and the net effect on patient management and patient outcomes is not certain. Therefore, impedance-pH testing is considered not medically necessary

Practice Guidelines and Position Statements

The American College of Gastroenterology 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.

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.

The American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD in 2008. (15) 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.

The National Institute for Health and Clinical Excellence (NICE) released technology appraisal guidance on catheterless esophageal pH monitoring in July 2006. (16) 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.

Medicare National Coverage

The Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination for 24-hour ambulatory pH monitoring in 1985. (17) CMS indicates 24-hour ambulatory pH monitoring is covered for suspected gastric reflux when conventional tests have not been able to confirm reflux.

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Billing Coding/Physician Documentation Information

- 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

- 91037** Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;
- 91038** Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- 11/1/03 New policy. Added to Medical Section. Wireless monitoring is considered investigational.
- 11/1/04 No policy statement changes.
- 4/1/05 No policy statement changes. New codes added.
- 11/1/05 No policy statement changes.
- 11/1/06 Policy statement revised to indicate that wireless monitoring is not medically necessary. Change is effective 2/1/2007.
- 11/1/07 No policy statement changes.
- 11/1/08 No policy statement changes.
- 11/1/09 No policy statement changes.
- 11/1/10 Policy revised to indicate wireless monitoring may be considered medically necessary in patients who meet criteria for testing but cannot tolerate catheter-based testing. Wireless monitoring in all other situations is considered not medically necessary; time interval in policy statement for this monitoring changed to read "48 to 96 hours."
- 11/1/11 New policy statement regarding impedance-pH testing as not medically necessary added. References to catheter based or wireless pH testing removed.
- 11/1/12 No policy statement changes.
- 11/1/13 Removed "24-hour" from the policy statement on impedance monitoring as catheter-based impedance monitoring for any length of time is considered not medically necessary. No other changes to policy statements.

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