Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/24**
(See policy history boxes for previous effective dates)

Title: Esophageal Function Tests

Description/Background

Test Descriptions

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of several days. Expert clinical opinion has suggested that catheter-based and wireless pH monitoring may aid in the diagnosis of gastroesophageal reflux disease (GERD) in patients who have an uncertain diagnosis after clinical evaluation and endoscopy. Esophageal pH monitoring is not considered a standard diagnostic test for most patients with GERD, but there is strong clinical support for its use in selected subpopulations for certain indications. Clinical guidelines support pH testing for patients with GERD being considered for surgical intervention. Wireless pH monitoring measurements appear to correlate closely to catheter-based monitoring and may be more comfortable for patients.

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 GERD.

Esophageal manometry measures the pressures and the pattern of muscle contractions in the esophagus and is indicated in the evaluation of dysphagia and noncardiac chest pain in patients without evidence of mechanical obstruction, ulceration or inflammation. It is also an important tool in the evaluation of GERD, both for correct placement of pH electrodes and as an essential part of preoperative evaluation prior to anti reflux procedures.

Background

Gastroesophageal Reflux Disease
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 to some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis, subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia.

Diagnosis
Gastroesophageal reflux disease 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 nondiagnostic, or results are discordant with the clinical evaluation (in these cases, further diagnostic testing may be of benefit).

Monitoring
Esophageal monitoring is performed using a tube with a pH electrode attached to its tip, which is then passed into the esophagus to approximately 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 over a 24-hour period. Wireless pH monitoring is achieved using endoscopic or manometric guidance to attach the pH measuring capsule to 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 on 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 can identify reflux events in which the liquid is only slightly acidic or nonacidic.

Manometry: Conventional, High Resolution Manometry and High Resolution Manometry with Esophageal Pressure Topography (HREPT)
Kahrilas and Pandolfino (2021), in the article "High Resolution Manometry," state:

"The fundamental difference between conventional manometry and high-resolution manometry (HRM) is the number of pressure sensors used and the spacing between them. In contrast to conventional manometry where three to eight sensors are spaced at 3 to 5 cm intervals, HRM sensors are typically spaced 1 cm apart along the length of the manometric assembly. Hence, catheters with up to 36 sensors allow for simultaneous pressure readings spanning both sphincters and the interposed esophagus.

Esophageal pressure topography (EPT) is a three-dimensional plotting format devised for depiction of HRM studies [HREPT]. EPT interpolates pressure values between sensors to create a pressure continuum. Pressure magnitude is converted into a color scale using cold colors to denote low pressures and hot colors to denote higher pressures. In an EPT plot, time and location within the esophagus are continuous variables and pressure magnitude is indicated at each x-y coordinate by color. The result is a seamless isobaric contour map

spanning from above the upper esophageal sphincter to below the esophagogastric junction . This also allows for the depiction of real-time luminal pressure gradients and spatial transition points of contraction amplitude or propagation velocity along the esophagus that correlate with anatomical and/or physiological landmarks.

Both EPT analysis and conventional manometry aim to characterize peristalsis and esophagogastric junction function. However, the types of measurements obtained differ substantially. Several novel metrics and nomenclature have been devised specifically to quantify esophageal function in EPT."[1]

Regulatory Status

Esophageal pH electrodes are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements.

Several wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared for marketing by FDA through the 510(k) process. Examples include the Bravo™ pH Monitoring System (Medtronic), 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. The ZepHr Refux Monitoring System (Diversatek) is an impedance device to detect reflux. FDA product code: FFX.

Medical Policy Statement

The safety and effectiveness of esophageal pH testing (catheter based as well as wireless techniques) with either conventional manometry or high-resolution manometry; and multichannel impedance testing (pH as well as pressure) have been established. They are considered useful diagnostic options when indicated.

High-resolution esophageal pressure topography (HREPT) is considered experimental/ investigational as its effectiveness beyond conventional testing analysis has not been established.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Esophageal testing (such as conventional and high-resolution manometry, esophageal pH testing and multichannel impedance testing) using a catheter-based system may be considered established 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 antireflux repair
  - Evaluation of patients after antireflux 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 therapy

  - Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a 1-month trial of proton pump inhibitor therapy
  - Evaluation of suspected otolaryngologic manifestations of GERD (ie, 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 (such as esophageal pH testing; conventional manometry or high-resolution manometry; and multichannel impedance testing, pH as well as pressure) may be considered established 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
  - Recurrent pneumonia
- 48- to 96-hour, catheter-free, wireless esophageal monitoring (gastroesophageal reflux test) may be considered established for use in esophageal pH monitoring for patients who are unable to complete catheter-based testing and meet the criteria listed above.

Exclusions:

- 3-dimensional high-resolution esophageal pressure topography (HREPT)
- 48- to 96-hour, catheter-free, wireless esophageal monitoring (gastroesophageal reflux test) is considered experimental/investigational except as noted in the inclusionary guidelines above

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

91010 91013 91034 91035 91037 91038

Other codes (investigational, not medically necessary, etc.):

91299

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Catheter-Based pH Monitoring for Gastroesophageal Reflux Disease

Clinical Context and Test Purpose
The purpose of catheter-based pH monitoring in individuals who have gastroesophageal reflux disease (GERD) is to inform a decision whether to proceed to appropriate treatment.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with GERD.

Interventions
The test being considered is catheter-based pH monitoring. Esophageal pH monitoring for 24 hours with catheter-based systems is primarily used in patients who have GERD that has not responded symptomatically to a program of medical therapy (including proton pump inhibitors [PPIs]); monitoring is also conducted in patients with refractory extra-esophageal symptoms.

Comparators
The following practice is currently being used to manage GERD: standard of care.

Outcomes
The general outcomes of interest are test validity, symptoms, and functional outcomes. Follow-up ranges over weeks to months for the outcomes of interest.
Study Selection Criteria
For the evaluation of clinical validity of the tests in this review, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard (describe the reference standard)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
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 current evidence regarding the diagnostic capability of catheter-based pH monitoring led Kahrilas and Quigley (1996), authors of a 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]

Although established technology, aspects of these catheter-based systems' use as a diagnostic test for GERD are problematic, and thus make it difficult to determine its utility or the utility of potential alternative tests. Without a reference standard for GERD, it is difficult to compare the diagnostic test performance of different types of tests. While it is possible to determine the degree to which the 2 tests correlate, it is difficult to determine if one is better than the other.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs were identified that assessed the clinical utility of catheter-based pH testing for this population.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.
Because the clinical validity of catheter-based pH testing for GERD has not been established, a chain of evidence supporting the test's clinical utility cannot be constructed.

Section Summary: Catheter-Based pH Monitoring for Gastroesophageal Reflux Disease
For individuals who have GERD who receive catheter-based pH monitoring, the evidence includes cross-sectional studies evaluating test performance in different populations. 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 chain of evidence supporting the utility of the test is weak.

Wireless pH Monitoring for Gastroesophageal Reflux Disease

Clinical Context and Test Purpose
The purpose of wireless pH monitoring in individuals who have GERD is to inform a decision whether to proceed to appropriate treatment.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with GERD.

Interventions
The test being considered is wireless pH monitoring.

Comparators
The following tests and practices are currently being used to manage GERD: catheter-based pH monitoring and standard of care.

Outcomes
The general outcomes of interest are test validity, symptoms, and functional outcomes. Follow-up ranges over weeks to months for the outcomes of interest.

Study Selection Criteria
For the evaluation of clinical validity of the test, the eligibility criteria considered are those outlined in the first indication.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews
A systematic review and meta-analysis by Kessels et al (2017) was unable to compare the accuracy of wireless pH testing with standard catheter monitoring due to variability across studies.[2] A Blue Cross Blue Shield Association TEC Special Report (2006) assessed wireless esophageal monitoring.[3] Six case series reviewed in the report demonstrated success rates of over 90% in completing a 48-hour pH study. Two studies that surveyed patients who received wireless pH monitoring and s who received traditional catheter monitoring showed less discomfort, less disruption of daily activities, and higher overall satisfaction with the wireless test. 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 revealed a fairly close correlation between the 2 types of studies after correcting for calibration differences; however, the ideal cut-point for test positivity differed for the tests.

Cohort Studies

Studies published since the 2006 TEC Special Report have shown similar findings on the correlation between wireless pH monitoring and standard catheter monitoring. Hakanson et al (2009) evaluated simultaneous wireless and traditional pH testing in 92 patients.[4] Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The 2 techniques correlated (r^2=0.66); however, the range between limits of agreement was wide. The techniques were concordant on the final diagnosis 82.1% of the time. Wenner et al (2007), in another 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%.[5] The sensitivity of wireless monitoring 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 (2007) showed similar diagnostic performance of wireless and traditional pH monitoring.[6]

Additional studies replicate findings that a longer period of monitoring increases the proportion of positive tests. Grigolon et al (2011) showed that, in 51 patients receiving prolonged monitoring, the 96-hour test reduced the number of indeterminate tests from 11 to 5.[7] In this particular study, comparison of outcomes for patients who received wireless monitoring, and a matched control group who received traditional catheter monitoring, showed similar outcomes and satisfaction. Sweis et al (2011) assessed wireless pH monitoring up to 96 hours in 38 patients with ongoing GERD symptoms who failed 24-hour catheter-based pH monitoring.[8] The results revealed an objective GERD diagnosis in 37% of patients at 96 hours. The authors concluded that prolonged wireless pH-monitoring increases sensitivity and diagnostic yield in patients experiencing esophageal symptoms despite negative 24-hour catheter-based pH testing, but the results should not be applied to all patients with negative catheter-based pH monitoring. Garrean et al (2008) 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, they were prescribed PPIs.[9] 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. Scarpulla et al (2007) attempted 96-hour monitoring in 83 patients.[10] Monitoring for the full 96 hours was successful in 41% of patients. In them, the proportion showing some degree of pathologic acid exposure increased as monitoring time increased.

Some studies have attempted to support an argument that a longer monitoring time with a wireless monitor would result in a 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 (2005) compared the diagnostic yield for a single day of monitoring with the complete 2 days of monitoring.[11] 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. A greater number of positive tests produced by a longer duration of the test is not evidence of a superior test.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs were identified that assessed the clinical utility of wireless pH testing for this population.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of wireless pH testing for GERD has not been established, a chain of evidence supporting the test's clinical utility cannot be constructed.

Section Summary: Wireless pH Monitoring for Gastroesophageal Reflux Disease
For individuals who have GERD who receive wireless pH monitoring, the evidence includes cross-sectional studies evaluating test performance and diagnostic yield in different populations. Positive wireless pH monitoring tests correlate with endoscopically defined GERD and 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 with 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 chain of evidence supporting the utility of the test is weak.

Impedance pH Testing for Gastroesophageal Reflux Disease

Clinical Context and Test Purpose
The purpose of impedance pH monitoring in individuals who have GERD is to inform a decision whether to proceed to appropriate treatment.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with GERD.

Interventions
The test being considered is impedance pH testing.

Comparators

The following tests and practices are currently being used to manage GERD: catheter-based pH monitoring and standard of care.

Outcomes
The general outcomes of interest are test validity, symptoms, and functional outcomes. Follow-up ranges over weeks to months for the outcomes of interest.

Study Selection Criteria
For the evaluation of clinical validity of the test, the eligibility criteria considered are those outlined in the first indication.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Evidence on the use of impedance pH testing suffers from issues similar to the evaluation of wireless pH testing: lack of a reference standard and lack of evidence that shows improved patient outcomes. Many studies have argued that an increase in positive tests, or diagnostic yield, is by itself evidence that supports the validity of the test. However, the increase in positive tests, if it indicates increased sensitivity, may decrease specificity. The net effect on patient management and patient outcomes is uncertain.
Several studies have demonstrated a higher yield for positive tests when using impedance pH testing and identifying reflux events that are nonacidic or only weakly acidic (and thus would not be detected using pH testing alone).[13,14,15] For example, Bajbouj et al (2007) studied 41 patients with atypical GERD symptoms with numerous tests.[13] The test that produced the highest number of positive findings was impedance pH testing. Bredenoord et al (2006) did a similar study in 48 patients.[14] A higher proportion of subjects had positive tests when using impedance pH data (77%) than when using pH data alone (67%). A study by Mainie et al (2006) showed similar findings.[15]

Studies have also examined performing impedance pH testing while patients are on acid suppression therapy. Vela et al (2001) demonstrated that during acid suppressive therapy, the total number of reflux episodes is similar, but fewer episodes of acidic reflux occur.[16] An observational cohort study by Gyawali et al (2021) reported that abnormal impedance pH testing while patients with proven GERD were taking twice daily PPIs was associated with lack of response to acid-suppression therapy.[17]

Although impedance pH testing produces a higher number of positive tests, particularly compared with traditional or wired pH testing in the setting of concurrent acid-suppressive therapy, there is insufficient evidence that these test results are more accurate.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs were identified that assessed the clinical utility of impedance pH testing for this population.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of impedance pH testing for GERD has not been established, a chain of evidence supporting the test's clinical utility cannot be constructed.

Section Summary: Impedance pH Testing for Gastroesophageal Reflux Disease
For individuals who have GERD who receive impedance pH testing, the evidence includes cross-sectional studies evaluating test performance and diagnostic yield in different populations. 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 with pH testing alone, but the effect of this finding on individual outcomes is uncertain. There are no studies of clinical utility showing improved outcomes, and the chain of evidence supporting the utility of the test is weak.

Esophageal Manometry
Esophageal manometry has been used to evaluate esophageal function and to identify motility disorders. Conklin (2013) concluded that "[high resolution manometry] HRM has made esophageal manometry easier for the technician and more tolerable for the patient. It provides us with a complete spatial and temporal view of esophageal motor function for the first time. In fact, almost all disorders of esophageal motor function produce different esophageal pressure topography (EPT) patterns that are easily recognized. Serious efforts to distinguish distinct esophageal motor disorders based on EPT led to the development of the Chicago classification, which remains a work in progress, and is not applicable to all esophageal motor disturbances like pharyngeal dysfunction, rumination and supragastric belches. It has not yet been applied to methods that challenge the esophagus like multiple rapid swallows, viscous swallows or solid swallows. Future work in this area, combining the Chicago classification system with challenge techniques, should improve our diagnosis and understanding of esophageal dysfunction."[18]

The American Society for Gastrointestinal Endoscopy Technology Committee (2012) published a report focusing on high resolution manometry, stating: "Studies are needed to determine whether HRM data are more reproducible and can provide a more complete understanding of esophageal motility disorders. For example, recent publications on HRM have proposed a new subclassification for achalasia. Further studies are necessary to determine whether these distinctions translate to superior diagnosis or treatment strategies for achalasia and other disorders. Few studies address the utility of HRM for diffuse esophageal spasm, and future research may determine whether this condition is a distinct entity or a possible variant of achalasia or lies within the spectrum of non-specific motility disorders. Better characterization of this and other non-specific esophageal conditions through HRM research may aid in

identifying effective treatment. Finally, further research is needed to determine whether HRM is superior to conventional manometry for the prediction of dysphagia after reflux surgery."[19]

Roman et al (2016) reported on a randomized multicenter study comparing the diagnosis performed with HRM and conventional manometry (CM) with confirmation at 6 months. A total of 247 patients were randomized and 245 analyzed: 122 in the CM arm and 123 in the HRM arm. A manometric diagnosis was more frequently initially achieved with HRM than with CM (97% vs 84%; p<.01). Achalasia was more frequent in the HRM arm (26% vs 12% in the CM arm; p<.01) while normal examinations were more frequent in the CM arm (52% vs 28% in the HRM arm; p<.05). After follow-up, the initial diagnosis was confirmed in 89% of patients in the HRM arm versus 81% in the CM arm (p=.07). Finally, overall procedure tolerance was better with CM than with HRM (p<.01). The authors concluded that the study results demonstrated an improved diagnostic yield for achalasia with HRM compared with CM. Diagnoses tended to be more frequently confirmed in patients who underwent HRM, suggesting that esophageal motility disorders could be identified earlier with HRM than with CM.[20]

Summary of Evidence

For individuals who have gastroesophageal reflux disease (GERD) who receive catheter-based pH monitoring, the evidence includes cross-sectional studies evaluating test performance in different populations. The relevant outcomes are test 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 chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have GERD who receive wireless pH monitoring, the evidence includes cross-sectional studies evaluating test performance and diagnostic yield in different populations. The relevant outcomes are test validity, symptoms, and functional outcomes. Positive wireless pH monitoring tests correlate with endoscopically defined GERD and 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 with 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 chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Expert clinical opinion has suggested that catheter-based and wireless pH monitoring may aid in the diagnosis of GERD in patients who have an uncertain diagnosis after clinical evaluation and endoscopy. Esophageal pH monitoring is not considered a standard diagnostic test for most patients with GERD, but there is strong clinical support for its use in selected subpopulations for certain indications. Clinical guidelines support pH testing for patients with GERD being considered for surgical intervention. Wireless pH monitoring measurements appear to correlate closely to catheter-based monitoring and may be more comfortable for patients or may be an option for patients unable to tolerate catheter-based monitoring.

For individuals who have GERD who receive impedance pH testing, the evidence includes cross-sectional studies evaluating test performance and diagnostic yield in different

populations. The relevant outcomes are test 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 with 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 chain of evidence supporting the utility of the test is weak.

Esophageal manometry has been used to evaluate esophageal function and to identify motility disorders. High resolution manometry technology may provide a better understanding of esophageal physiology as well as the potential for improvement in diagnosis and treatment of various motility disorders. Further studies are needed to determine the full potential of HRM in clinical practice.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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.

In response to requests, the Blue Cross Blue Shield Association received input from 1 physician specialty society (2 reviewers) and 3 academic medical centers while their policy was under review in 2010. The input was mixed. Most 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. Moreover, most agreed that a linkage between wireless monitoring and improved health outcome had not been demonstrated.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2020, the American College of Gastroenterology (ACG) released a clinical guideline on the clinical use of esophageal physiologic testing.[21] The guideline conditionally recommends using prolonged wireless pH monitoring over catheter-based monitoring to diagnose gastroesophageal reflux disease (GERD) in adults with infrequent or day-to-day variations in esophageal symptoms. The recommendation is based on a very low quality of evidence. Wireless pH monitoring is especially beneficial in patients unable to tolerate a transnasal catheter or if a transnasal catheter yields negative results despite a high suspicion of GERD.

The ACG suggests using ambulatory pH impedance monitoring on proton pump inhibitor (PPI) therapy over endoscopic evaluation or pH monitoring alone to diagnose persisting GERD in

adults with typical esophageal reflux symptoms and previous confirmatory evidence of GERD (conditional recommendation, very low quality of evidence).

The ACG updated the guideline for the diagnosis and management of GERD in 2021 with recommendations support the use of pH monitoring to aid in the diagnosis of GERD as well as the management of refractory GERD.[22] In the diagnosis of GERD, the ACG recommendations pertinent of pH testing include:

- "In patients who have chest pain without heartburn and who have had adequate evaluation to exclude heart disease, objective testing for GERD (endoscopy and/or reflux monitoring) is recommended (conditional recommendation, low level of evidence)."
- "In patients form whom the diagnosis of GERD is suspected but not clear, and endoscopy shows no objective evidence of GERD, we recommend reflux monitoring be performed off therapy to establish the diagnosis (strong recommendation, low level of evidence)."
- "We recommend against performing reflux monitoring off therapy solely as a diagnostic test for GERD in patients known to have endoscopic evide3nce of Los Angeles (LA) grade C or D reflux esophagitis or in patients with long-segment Barrett's esophagus (strong recommendation, low level of evidence)."

For patients with refractory GERD the ACG recommends:

- ""We suggest esophageal pH monitoring (Bravo, catheter-based, or combined impedance-pH monitoring) preformed OFF PPIs if the diagnosis of GERD has not been established by a previous pH monitoring study or an endoscopy showing long-segment Barrett's esophagus or severe reflux esophagitis (LA grade C or D) (conditional recommendation, low level of evidence)."
- "We suggest esophageal impedance-pH monitoring performed on PPIs for patients with an established diagnosis of GERD whose symptoms have not responded adequately to twice-daily PPI therapy (conditionally recommendation, low level of evidence)."

American Gastroenterological Association

In 2022 the American Gastroenterological Association (AGA) updated recommendations for GERD and include reflux monitoring in their best practice advice as follows:[23]

- "If PPI therapy is continued in a patient with unproven GERD, clinicians should evaluate the appropriateness and dosing within 12 months after initiation, and offer endoscopy with prolonged wireless reflux monitoring off PPI therapy to establish appropriateness of long-term PPI therapy."
- "If troublesome heartburn, regurgitation, and/or non-cardiac chest pain do not respond adequately to a PPI trial or when alarm symptoms exist, clinicians should investigate with endoscopy and, in the absence of erosive reflux disease (Los Angeles B or greater) or long-segment ($\geq$3 cm) Barrett's esophagus, perform prolonged wireless pH monitoring off medication (96-hour preferred if available) to confirm and phenotype GERD or to rule out GERD."
- "Clinicians should perform upfront objective reflux testing off medication (rather than an empiric PPI trial) in patients with isolated extra-esophageal symptoms and suspicion for reflux etiology."
- "In symptomatic patients with proven GERD, clinicians should consider ambulatory 24-hour pH impedance monitoring on PPI as an option to determine the mechanism of

persisting esophageal symptoms despite therapy (if adequate expertise exists for interpretation)."

No strength of recommendation rations were provided.

The AGA (2022) also developed recommendations for ambulatory reflux monitoring in patients with undiagnosed GERD persisting despite PPI therapy and in those with GERD who have inadequate PPI response[24]. They recommend 96-hour wireless pHmonitoring to determine future therapy and further diagnostic strategy in undiagnosed GERD. There was 100% committee agreement on wireless pH monitoring as the preferred diagnostic tool in patients with unproven GERD not responding to PPIs. In patients with established GERD, 24-hour impedance monitoring on PPI therapy was considered useful to define refractory GERD (88% committee agreement).

In 2023, the AGA released a clinical practice update on diagnosis and management of extraesophageal GERD.[25.] Patients with an established GERD diagnosis who do not respond to high-dose acid suppression can be considered for testing. The authors do not state a preference for a specific testing modality (impedance, catheter, and wireless capsule are all mentioned) but highlight that impedance testing can detect weakly acidic, nonacidic, and proximal reflux. Impedance monitoring is also the only specific testing modality that is noted for use while on acid suppression.

The Lyon Consensus

In 2018, an expert panel known as the Lyon Consensus provided GERD diagnosis recommendations that updated a prior consensus (the 2002 Porto consensus, published in 2004) and incorporated several prior consensus statements including Roman et al 2017 and Savarino et al 2017 (both summarized below).[26] The Lyon Consensus was updated in 2023 to the 2.0 version.[27] Changes from the prior version included providing comments on wireless pH monitoring and providing indications, nocturnal thresholds, and guidance for on-treatment use of pH-impedance monitoring. The 2.0 panel stated that prolonged wireless pH monitoring off antisecretory therapy is the preferred diagnostic tool in unproven GERD, and may be most effective when conducted for 96 hours. Diagnosis of unproven GERD may be aided by pH-impedance monitoring (off antisecretory therapy) when atypical symptoms are present (eg, excessive belching, rumination, pulmonary symptoms). pH-impedance testing while in PPI therapy is recommended for individuals with persistent GERD symptoms. The specific wireless pH monitoring acid exposure time threshold that is diagnostic for GERD is >6% on 2 or more days. Similarly, the ambulatory pH-impedance monitoring threshold (off PPI) that is diagnostic for GERD is >6% total acid exposure time. Refractory GERD is diagnosed with acid exposure time >4% and >80 reflux episodes per day while on an optimal antisecretory therapy.

International Consensus Group
In 2017, an international consensus group updated prior recommendations for GERD testing (the 2002 Porto consensus, published in 2004) to include statements on the role of ambulatory reflux monitoring in GERD diagnosis.[24] Recommendations on the choice of GERD testing modality were based on moderate quality evidence or lower (none were supported by high quality evidence) and are as follows:

- Esophageal pH impedance monitoring may be indicated for patients with refractory symptoms despite PPI therapy, before and/or after antireflux surgery, and for some specific symptoms (i.e., cough, frequent belching, rumination syndrome).
- Wireless pH monitoring is indicated for patients who cannot tolerate pH catheters or who have a negative catheter pH study and ongoing symptoms.
- pH monitoring (catheter, wireless, or impedance) should be performed in most individuals at least 7 days after the last PPI dose. Impedance pH monitoring can be performed while the patient is taking a double-dose PPI if there is prior evidence of reflux such as prior pH testing, severe esophagitis, histology-proven Barrett's esophagus >1 cm, or peptic stricture.

International Working Group for Disorders of Gastrointestinal Motility and Function
In 2017, an expert consensus panel authored a statement on physiological assessment and diagnosis of GERD.[28] The group's algorithm for assessing symptoms suggestive of GERD states that patients with atypical or alarming symptoms should first undergo endoscopy. Patients with documented reflux who do not respond to antireflux therapy should undergo ambulatory pH impedance monitoring while taking a PPI. Impedance pH testing is also indicated for patients without evidence of reflux who do not respond to empiric PPI therapy. Wireless pH monitoring is suggested for patients with negative 24-hour impedance pH monitoring who are still suspected of having GERD.

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, et al
In 2018, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology Hepatology, and Nutrition (ESPGHAN) released a guideline on management of GERD in children.[29] Based on expert opinion, the guideline strongly recommends using pH impedance monitoring to correlate troubling symptoms with acid reflux events. The guideline includes weak recommendations for pH impedance monitoring for clarifying the role of acid reflux in esophagitis and other GERD symptoms, clarifying the diagnosis in patients with normal endoscopy findings, and determining the effect of acid suppression therapy. If pH impedance monitoring is not available, the guideline strongly recommends that wireless pH monitoring be used only to correlate troubling symptoms with acid reflux events, confirm whether symptoms occur at the time of acid reflux events, and to determine the effect of acid suppression therapy. There is not enough evidence to support routine use of either pH monitoring technique for diagnosis of GERD in infants and children.

National Institute for Health and Care Excellence
In 2006, NICE released guidance on catheter-less esophageal pH monitoring.[30] This guidance indicated catheter-less esophageal pH monitoring appears to be safe and effective and is commonly indicated for GERD symptoms refractory to PPIs and for GERD symptom recurrence after antireflux surgery.

In 2019, the NICE updated guidance on the diagnosis and management of GERD in children and young people.[31] The recommendations specific to esophageal pH monitoring included:

“Consider performing an esophageal pH study (or combined esophageal pH and impedance monitoring if available) in infants, children and young people with:

- suspected recurrent aspiration pneumonia
- unexplained apneas
- unexplained non-epileptic seizure-like events
- unexplained upper airway inflammation
- dental erosion associated with a neurodisability
- frequent otitis media
- a possible need for fundoplication
- a suspected diagnosis of Sandifer’s syndrome

Consider performing an esophageal pH study without impedance monitoring in infants, children and young people if, using clinical judgement, it is thought necessary to ensure effective acid suppression.”

RAND Appropriateness Method Consensus

A National Institutes of Health-funded consensus panel comprised of United States physician experts that used a RAND/University of California Los Angeles appropriateness method (a modified Delphi method) to develop consensus statements regarding the clinical role of ambulatory reflux monitoring in patients with nonresponse to PPIs.[24] The consensus recommendations were published in 2023. Recommendation statements were graded on a 9-point scale (scores of 1 to 3 were inappropriate, scores of 4 to 6 were uncertain appropriateness, and scores of 7 to 9 were appropriate). Recommendations were considered appropriate if the expected health benefit exceeded the expected negative consequences after taking into account the cost. Among the final 15 recommendation statements, 8 were appropriate and 7 were uncertain. The appropriate recommendations were as follows:

- Prolonged wireless pH monitoring off PPI is preferred for the diagnosis of unproven GERD and in patients with typical reflux symptoms not adequately controlled with single-dose PPI therapy.
- The preferred duration of wireless pH monitoring off acid suppression is 96 hours.
- An acid exposure time <4% on all days of monitoring and an overall negative symptom association does not support PPI therapy.
- An acid exposure time >6% across 2 or more days is diagnostic and supports treatment for GERD.
- An acid exposure time >10% across 2 or more days indicates severe acid burden and justifies escalating anti-reflux treatment.
- 24-hour pH impedance on PPI therapy is useful for diagnosing refractory GERD.
- In patients with proven GERD and lack of response to optimal PPI therapy, an acid exposure time <2% (on pH impedance monitoring and double-dose PPI therapy) and an overall negative symptom association, or <40 reflux events, does not support escalating anti-reflux treatment.
- In patients with proven GERD and lack of response to optimal PPI therapy, an acid exposure time >4% (on pH impedance monitoring and double-dose PPI therapy) and an overall positive symptom association supports escalating anti-reflux treatment.

U.S. Preventive Services Task Force

Not applicable.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

Government Regulations

National:

Medicare does not have a policy addressing esophageal impedance monitoring.

National Coverage Determination (NCD)
24-Hour Ambulatory Esophageal pH Monitoring (100.3), effective date 6/11/1985

Item/Service Description
Twenty-four hour ambulatory esophageal pH monitoring is a diagnostic procedure involving the placement on an indwelling electrode into the lower esophagus of a patient for the purposed of determining the presence of gastric reflux and measuring abnormal esophageal acid exposure.

Indications and Limitations of Coverage
Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

National Coverage Determination (NCD)
Esophageal Manometry (100.4), effective date 10/2/1978

Item/Service Description
The major use of esophageal manometry is to measure pressure within the esophagus to assist in the diagnosis of esophageal pathology including aperistalsis, spasm, achalasia, esophagitis, esophageal ulcer, esophageal congenital webs, diverticuli, scleroderma, hiatus hernia, congenital cysts, benign and malignant tumor, hypermobility, and extrinsic lesions. Esophageal manometry is mostly used in difficult diagnostic cases and as an adjunct to X-rays and direct visualization of the esophagus (endoscopy) through the fiberscope.

Indications and Limitation of Coverage
Esophageal manometry is covered under Medicare where it is determined to be reasonable and necessary for the individual patient.

[*There is no mention of high-resolution manometry*.]

Local:

There are no local coverage determinations (LCDs) on these topics.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Ingestible Capsule for Assessment of Gastrointestinal (Motility) Disorders
- Magnetic Esophageal Sphincter Augmentation Treat Gastroesophageal Reflux Disease (GERD)
- Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia or Gastroparesis
- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD) (Transoral Incisionless Fundoplication - TIF)
- Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 11/15/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/07	3/21/07	5/1/07	Joint policy established
5/1/08	2/19/08	3/14/08	Routine maintenance
7/1/09	4/21/09	5/11/09	Routine maintenance
9/1/09	7/16/09	6/16/09	Changed status from experimental to established; the following policies were combined into this policy: Esophageal Function Test by Intraluminal Impedance Esophageal pH Monitoring
5/1/11	2/15/11	3/3/11	Routine maintenance; updated criteria for wireless esophageal testing; added new codes 0240T and 0241T for 3-D motility studies as experimental/investigational; added CPT codes 91010 and 91013 for 2-D esophageal motility studies as established
5/1/12	2/21/12	2/21/12	Routine maintenance, revisions to nomenclature for CPT codes 91010 and 91013
11/1/14	8/21/14	8/25/14	Routine maintenance
7/1/15	4/21/15	5/8/15	• Routine maintenance • Deleted code 91299 • Updated sections: Description/Background, medical policy statement, rationale, summary, practice guidelines and position statements to include esophageal manometry (conventional and high-resolution) • Updated coverage determination for mixed status • Updated references

7/1/16	4/19/16	4/19/16	• Routine policy maintenance • Deleted procedure codes 0240T and 0241T; added NOC code 91299 • Updated references & rationale sections • No change in policy status
7/1/17	4/18/17	4/18/17	• Routine maintenance • References and rationale updated.
7/1/18	4/17/18	4/17/18	• Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance; clarified high resolution manometry
11/1/19	8/20/19		Routine maintenance
11/1/20	8/18/20		Routine maintenance
11/1/21	8/17/21		Routine maintenance. Ref 8 added
5/1/22	2/15/22		Routine maintenance. Ref 17,24,25,26,27,28,29 added
5/1/23	2/21/23		Routine maintenance (jf) Ref 22, 23, 24 added Vendor Managed: NA
5/1/24	2/20/24		Routine maintenance (jf) Vendor Managed: NA Ref Added: 24,25,27

Next Review Date: 1st Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ESOPHAGEAL FUNCTION TESTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Established codes covered, apply criteria See Inclusionary & Exclusionary Guidelines
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Established codes covered, apply criteria See Inclusionary & Exclusionary Guidelines

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.