Medical Policy

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Title: Esophageal pH Monitoring

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Populations	Interventions	Comparators	Outcomes
Individuals: • With gastroesophageal reflux disease	Interventions of interest are: • Catheter-based pH monitoring	Comparators of interest are: • Standard of care	Relevant outcomes include: • Test validity • Symptoms • Functional outcomes
Individuals: • With gastroesophageal reflux disease	Interventions of interest are: • Wireless pH monitoring	Comparators of interest are: • Catheter-based pH monitoring • Standard of care	Relevant outcomes include: • Test validity • Symptoms • Functional outcomes
Individuals: • With gastroesophageal reflux disease	Interventions of interest are: • Impedance pH testing	Comparators of interest are: • Catheter-based pH monitoring • Standard of care	Relevant outcomes include: • Test validity • Symptoms • Functional outcomes

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DESCRIPTION

Esophageal pH monitoring, using wired or wireless devices, can record the pH of the lower esophagus for a period of 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).

OBJECTIVE

The objective of this evidence review is to determine whether testing with catheter-based pH monitoring, wireless pH monitoring, or impedance pH testing improves the net health outcome in individuals-specifically those with known or suspected gastroesophageal reflux disease.

BACKGROUND

Gastroesophageal Reflux Disease

Acid reflux is the cause of heartburn and acid regurgitation esophagitis, which can lead to esophageal stricture. Acid reflux can also cause or contribute 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 done 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.

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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 the 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® Reflux Monitoring System (Diversatek) is an impedance device to detect reflux. FDA product code: FFX.

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POLICY

A. Esophageal pH monitoring using a catheter or wireless-based system may be considered **medically necessary** in adults, children or adolescents able to report symptoms[a] for one of the following clinical indications:
   1. Documentation of abnormal acid exposure in endoscopy-negative individuals being considered for surgical antireflux repair
   2. Evaluation of individuals after antireflux surgery who are suspected of having ongoing abnormal reflux
   3. Evaluation of individuals with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy
   4. Evaluation of refractory reflux in individuals with chest pain after cardiac evaluation and after a 1-month trial of proton pump inhibitor therapy
   5. Evaluation of suspected otolaryngologic manifestations of gastroesophageal reflux disease (i.e., laryngitis, pharyngitis, chronic cough) in individuals who have failed to respond to at least 4 weeks of proton pump inhibitor therapy
   6. Evaluation of concomitant gastroesophageal reflux disease in individuals with adult-onset, nonallergic asthma suspected of having reflux-induced asthma

B. Twenty-four-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:
   1. Unexplained apnea
   2. Bradycardia
   3. Refractory coughing or wheezing, stridor, or recurrent choking (aspiration)
   4. Persistent or recurrent laryngitis
   5. Recurrent pneumonia

C. Catheter-based impedance-pH monitoring is considered **experimental / investigational**.

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

POLICY GUIDELINES

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

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through July 8, 2026.

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 individuals who have GERD that has not responded symptomatically to a program of medical therapy (including proton pump inhibitors [PPIs]); monitoring is also conducted in individuals 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.

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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. 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 for 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."

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

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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 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

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. A TEC Special Report (2006) assessed wireless esophageal pH monitoring. 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 patients 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

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cases and normal controls showed similar results (results were also similar in 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. Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The 2 techniques correlated (r2=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 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%. 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) revealed a similar diagnostic performance of wireless and traditional pH monitoring.

Additional studies have replicated 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. 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. 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, patients were off therapy, and during the second 2 days, they were prescribed PPIs. As expected, during the second and third days, fewer patients showed reflux symptoms. It is difficult to determine from data analysis how such a testing protocol improves the diagnosis of GERD. Scarpulla et al (2007) attempted 96-hour monitoring in 83 patients. 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. Hashimoto et al (2025) published a prospective study assessing prolonged wireless capsule pH monitoring in patients with borderline acid exposure time (AET) for GERD, defined as 4% to 6% by the Lyon Consensus, in 33 symptomatic individuals identified from a prior 24-hour impedance-pH study. All patients underwent 96-hour wireless pH monitoring off PPIs. GERD was defined as AET >6% on at least 2 days, and non-GERD as AET <4% on all 4 days. Among 30 evaluable patients, 16 (53%) were reclassified as GERD, 6 (20%) as non-GERD, and 8 (27%) remained borderline, resulting in a conclusive diagnosis in 73%.

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

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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. The authors 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 a systematic review and 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.

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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 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
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). For example, Bajbouj et al (2007) studied 41 patients with atypical GERD symptoms with numerous tests. The test producing the highest number of positive findings

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was impedance pH testing. Bredenoord et al (2006) did a similar study in 48 patients. 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) reported similar findings.

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. 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.

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 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.

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.

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CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

2010 Input

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, input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review for 2010. Input was mixed. Most reviewers indicated that the wireless device was more comfortable and allowed individuals to do more varied activities during the recording. One reviewer cited problems with availability of the catheter-based systems. Moreover, most reviewers agreed that a link 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. 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 its guideline for the diagnosis and management of GERD in 2021 with recommendations supporting the use of pH monitoring to aid in the diagnosis of GERD as well as the management of refractory GERD. In the diagnosis of GERD, the ACG recommendations pertinent to 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 for 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)."

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- "We recommend against performing reflux monitoring off therapy solely as a diagnostic test for GERD in patients known to have endoscopic evidence 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) performed 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 (conditional 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:

- "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 (≥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 ratings were provided.

In 2023, the AGA released a clinical practice update on diagnosis and management of extraesophageal GERD. 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

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summarized below). The Lyon Consensus was updated in 2023 to the 2.0 version. 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. 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 the physiological assessment and diagnosis of GERD. 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.

International Working Group for the Classification of Oesophagitis

In 2024, the International Working Group for the Classification of Oesophagitis (IWGCO) published an evidence-based consensus statements regarding the management of patients with refractory reflux-like symptoms despite PPI therapy, including patients with refractory GERD. The following recommendations were made with regard to pH testing:

- "In patients with refractory reflux-like symptoms, we suggest that oesophageal pH testing should be performed off PPI therapy to determine whether the patient has excess acid gastroesophageal reflux as a cause for symptoms (conditional recommendations supported by very low quality of evidence)"

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- "In patients with refractory reflux-like symptoms for whom testing is performed on PPI therapy, we suggest oesophageal pH-impedance rather than oesophageal pH testing to identify reflux as a cause for the symptoms (conditional recommendations supported by very low quality of evidence)."

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 the management of GERD in children. 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 determine the effect of acid suppression therapy. There is not enough evidence to support the routine use of either pH monitoring technique for the 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. 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. 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 apnea
- 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. The consensus recommendations were published in 2023. Recommendation statements were graded on a 9-point scale (scores of 1 to 3 were inappropriate,

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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 Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2026 did not identify any ongoing or unpublished trials that would likely influence this review.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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)

REVISIONS	
10-11-11	Updated the Description section.
	In the Policy section: • In Item A, inserted "using a catheter-based or a catheter free wireless system" to read "Esophageal pH monitoring using a catheter-based or a catheter free wireless system…" • In Item A, removed "is" and inserted "may be" to read 'may be considered medically necessary…" • In Item A, inserted "in adults and children or adolescents able to report symptoms" • Added Item B, "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: o Unexplained apnea; o Bradycardia o Refractory coughing or wheezing; stridor, or recurrent choking (aspiration); o Persistent or recurrent laryngitis; and o Recurrent pneumonia." • Added Item C, "24-hour catheter-based impedance-pH monitoring is considered not medically necessary."
	Added Policy Guidelines.
	Updated Rationale section.
	In Coding section: • Removed CPT code 43225. • Added CPT codes: 43235, 91037, 91038. • Added the following diagnosis codes: 427.89 507.0, 770.81-770.89, 784.99, 786.03.

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REVISIONS	
	Added Revisions section.
	Updated Reference section.
09-17-2013	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 Diagnosis codes *(Effective October 1, 2014)*
	Updated Reference section.
01-01-2015	In Coding section: ▪ Revised CPT Code: 43235 (Effective January 1, 2015)
11-05-2015	Description section updated
	In Policy section: ▪ In Item A removed "or a catheter-free wireless" and added "wireless or" and an "*" to read, "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*:" ▪ In A 4 added "(PPI)". ▪ In A 5 and A 5 removed "proton pump inhibitor" and replaced with "PPI". ▪ In C removed "24-hour" to read "Catheter-based impedance-pH monitoring…" ▪ At the end of the policy language added the asterisk reference of "*Esophageal pH monitoring systems should be used in accordance with U.S. Food and Drug Administration–approved indications and age ranges." ▪ In Policy Guidelines added "The device may be placed with either endoscopic or manometry guidance." previously located in the Coding notations section.
	Rationale section updated
	In Coding section: ▪ Removed CPT Code: 43235 ▪ Updated Coding notations.
	References updated.
04-28-2017	Description section updated
	In Policy section: ▪ In Item A 5 removed "that" and added "gastroesophageal reflux disease" and "inpatients who" to read "Evaluation of suspected otolaryngologic manifestations of gastroesophageal reflux disease (GERD, i.e., laryngitis, pharyngitis, chronic cough) in patients who have failed to respond to at least 4 weeks of PPI therapy" ▪ In Item A 6 removed "an" and added "patients with" to read "Evaluation of concomitant GERD in patients with adult-onset, nonallergic asthmatic suspected of having reflux-induced asthma" ▪ In Item B replaced "24" with "Twenty-four" ▪ The updates did not have any impact on the intent of the policy.
	Rationale section updated
	In Coding section: ▪ Updated coding notation
	References updated
12-20-2017	Description section updated
	▪ In policy section revised abbreviations to meaning of abbreviations, i.e. "PPI" to "proton pump inhibitor" and "GERD" to "gastroesophageal reflux disease". This update had no change on intent of policy.
	Rationale section updated
	References updated
01-30-2019	Description section updated
	In Policy Section:

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REVISIONS	
	▪ In Item A revised wording from "wireless or catheter" to "catheter or wireless"
	Rationale section updated
	In Coding section: ▪ Added ICD Codes: G47.30, G47.31, G47.32, G47.33, K21.0, P28.0, P28.10, P28.11, P28.19, P28.9, R06.2
	References updated
02-24-2021	Updated Description section
	Updated Rationale section
	Updated Reference section
01-04-2022	Updated Description Section
	Updated Rationale
	Updated References
12-29-2022	Updated Description Section
	Updated Rationale Section
	Update Coding Section ▪ Convert the following ICD-10 codes, P28.0-P28.9 and J45.20-J45.902, to ranges to include all codes within the range
	Updated References Section
01-05-2024	Updated Description Section
	Updated Rationale Section
	Update Coding Section ▪ Removed ICD-10 codes
	Updated References Section
12-23-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
01-05-2026	Updated Description Section
	Updated Policy Section ▪ Section C: Catheter-based impedance-pH monitoring is considered Removed: "not medically necessary." Added: "experimental / investigational."
	Updated Rationale Section
	Updated Reference Section
10-27-2026	Updated Description Section
	Updated Policy Section ▪ Statement A changed from: Esophageal pH monitoring using a catheter or wireless-based system may be considered medically necessary for the following clinical indications in adults, and children or adolescents able to report symptoms[a] : ▪ To: Esophageal pH monitoring using a catheter or wireless-based system may be considered medically necessary in adults, children or adolescents able to report symptoms[a] for one of the following clinical indications:
	Updated Rationale Section
	Updated References Section

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