Policy Number	**MED201.005**
Policy Effective Date	**10/01/2025**
Policy End Date	**12/31/2025**

Esophageal pH Monitoring

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Related Policies (if applicable)
None

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Carefully check state regulations and/or the member contract.
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Coverage

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]

- Documentation of abnormal acid exposure in endoscopy-negative individuals being considered for surgical antireflux repair;
- Evaluation of individuals after antireflux surgery who are suspected of having ongoing abnormal reflux;
- Evaluation of individuals with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy;
- Evaluation of refractory reflux in individuals with chest pain after cardiac evaluation and after a 1-month trial of PPI therapy;
- Evaluation of suspected otolaryngologic manifestations of gastroesophageal reflux disease (GERD) (i.e., laryngitis, pharyngitis, chronic cough) that have failed to respond to at least 4 weeks of proton pump inhibitor therapy; or

- Evaluation of concomitant GERD in individuals with adult-onset, nonallergic asthma suspected of having reflux-induced asthma.

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:

- Unexplained apnea;
- Bradycardia;
- Refractory coughing or wheezing, stridor, or recurrent choking (aspiration);
- Persistent or recurrent laryngitis; and/or
- Recurrent pneumonia.

Twenty-four-hour catheter-based impedance pH monitoring **may be considered medically necessary** in individuals with established GERD on PPI therapy, whose symptoms have not adequately responded to therapy, in order to define refractory GERD.

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

Policy Guidelines

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

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).

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.

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.

Rationale

Medical policies 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. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these policies, 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 policy.

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.

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).

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 (Phila Pa 1976) 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." (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 policy.

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).

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)

Cohort Studies
Hakanson et al. (2009) evaluated simultaneous wireless and traditional pH testing in 92 patients. (3) 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 a study of 64 patients with GERD and 50 asymptomatic controls, showed a sensitivity of 59% to 65% when setting the specificity to 90% to 95%. (4) 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. (5)

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. (6) 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. (7) 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. (8) 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. (9) 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. (10) 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.

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 policy.

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).

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). (11-13) For example, Bajbouj et al. (2007) studied 41 patients with atypical GERD symptoms with numerous tests. (11) The test producing the highest number of positive findings was impedance pH testing. Bredenoord et al. (2006) did a similar study in 48 patients. (12) 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. (13)

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. (14) 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. (15)

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.

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. 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 a systematic review and cross-sectional studies evaluating test performance and diagnostic yield in different populations. 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.

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. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input

Clinical input obtained in 2010 has suggested that catheter-based and wireless pH monitoring may aid in the diagnosis of GERD in individuals who have an uncertain diagnosis after clinical evaluation and endoscopy. Esophageal pH monitoring is not considered a standard diagnostic test for most individuals with GERD, but there is strong clinical support for its use in selected subpopulations for certain indications. Clinical guidelines support pH testing for individuals 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 individuals or may be an option for individuals unable to tolerate catheter-based monitoring.

Practice Guidelines and Position Statements

American College of Gastroenterology

In 2020, the American College of Gastroenterology (ACG) released a clinical guideline on the clinical use of esophageal physiologic testing. (16) 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 supporting the use of pH monitoring to aid in the diagnosis of GERD as well as the management of refractory GERD. (17) 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)."
- "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)."

<u>American Gastroenterological Association</u>

In 2022, the American Gastroenterological Association (AGA) updated recommendations for GERD and include reflux monitoring in their best practice advice as follows: (18)

- "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 was 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. (19) They recommend 96-hour wireless pH monitoring 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. (20) 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.

<u>The Lyon Consensus</u>

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). (21) The Lyon Consensus was updated in 2023 to the 2.0 version. (22) 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 (e.g., 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. (23) 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. (24) 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. (25) 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 (NICE)

In 2006, NICE released guidance on catheter-less esophageal pH monitoring. (26) 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. (27) 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."

<u>RAND Appropriateness Method Consensus</u>

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. (19) 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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	91034, 91035, 91037, 91038
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/01/2025	Document updated with literature review. The following changes were made to Coverage: 1) Modified medical necessity criteria for esophageal pH monitoring using a wireless or catheter-based system in adults and children or adolescents able to report symptoms, specifically bullets 1 and 3; 2) Modified medical necessity criteria for catheter-based impedance-pH

	monitoring; and 3) Removed “not medically necessary” statement. No new references added.
10/15/2024	Document updated with literature review. Coverage unchanged. References 15, 17-20 and 22 added; some updated and others removed.
07/15/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. References 18-23 added; some updated and others removed.
02/01/2022	Reviewed. No changes.
03/15/2021	Document updated with literature review. Coverage unchanged. References 8 and 16 added; others updated.
07/15/2020	Reviewed. No changes.
04/15/2019	Document updated with literature review. The following change was made to Coverage: Replaced “endoscopy-negative patients” with “patients with either normal or equivocal endoscopic findings”. Reference 2 and 19 added.
04/15/2018	Reviewed. No changes.
08/01/2017	Document updated with literature review. Coverage unchanged.
10/01/2016	Reviewed. No changes.
02/01/2016	Document updated with literature review. The following was added to Coverage: treatment with a proton pump inhibitor (PPI) at the maximum recommended dose, for at least 4 weeks was added to the third bullet under the following statement: 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*. The title was changed from Esophageal Monitoring.
02/01/2014	Document updated with literature review. The following were removed from coverage section: 1) 4 week requirement of proton pump inhibitor therapy previously required for “evaluation of concomitant GERD in an adult-onset, nonallergic asthmatic suspected of having reflux-induced asthma” and 2) evaluation of the contraction of the muscles in the esophagus to establish motility. The following was added to the coverage section: 1) Catheter-based impedance-pH monitoring may be considered medically necessary in the evaluation of endoscopy-negative patients with GERD complaints refractory to PPI therapy in which documentation of non-acid reflux will alter clinical management 2) Catheter-based impedance-pH monitoring is considered not medically necessary for all other indications and 3) *Esophageal pH monitoring systems should be used in accordance with FDA-approved indications and age ranges.
11/01/2008	Editorial revision
04/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
06/01/2007	Coverage revised
11/01/2006	Revised/updated entire document
10/24/2006	Revised/updated entire document

05/01/1996	Revised/updated entire document
03/01/1995	Revised/updated entire document
12/01/1990	New medical document