Ambulatory Esophageal pH Monitoring

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DESCRIPTION

Acid reflux is the cause of heartburn, acid regurgitation peptic esophagitis, and Barrett's esophagus, and can cause esophageal stricture, some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia.

When acid repeatedly refluxes from the stomach into the esophagus alone, it is known as gastroesophageal reflux disease (GERD). However, if the stomach acid travels up the esophagus and spills into the throat or pharynx/larynx, is known as laryngopharyngeal reflux (LPR).

Gastroesophageal reflux disease is most commonly diagnosed by a 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).

Esophageal motility disorders often manifest with chest pain and dysphagia. Achalasia is a disorder of the lower esophageal sphincter and the smooth musculature of the esophageal body. In achalasia the lower esophageal sphincter typically fails to relax with swallowing, and the esophageal body fails to undergo peristalsis. Achalasia can be progressive and cause pronounced morbidity. Spastic disorders of the esophagus, such as diffuse esophageal spasm and nutcracker esophagus, and nonspecific esophageal motility disorder may represent a manifestation of gastroesophageal reflux disease (GERD).

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 (e.g., Bravo™ pH Monitoring System, marketed by Medtronic) 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. **Note:** *The Bravo™ pH Monitoring System, marketed by Medtronic is approved by the U.S. Food and Drug Administration (FDA) for the purposes of esophageal monitoring in those 4 years old and greater.*

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.

Clinical Context and Test Purpose

- **Catheter – Based pH Monitoring for Gastroesophageal Reflux Disease (GERD):** The purpose of catheter-based pH monitoring in patients who have gastroesophageal reflux disease (GERD) is to inform a decision whether to proceed to appropriate treatment.
- **Wireless pH Monitoring for Gastroesophageal Reflux Disease (GERD):** The purpose of wireless pH monitoring in patients who have gastroesophageal reflux disease (GERD) is to inform a decision whether to proceed to appropriate treatment.
- **Impedance pH Testing for Gastroesophageal Reflux Disease and Achalasia**
    - The purpose of impedance pH monitoring in children and adolescents $\leq$ 21 years of age for the evaluation of extraesophageal symptoms (laryngitis, pharyngitis, chronic cough) with symptoms similar to gastroesophageal reflux disease (GERD) to rule out esophageal motility disorders. is to inform a decision whether to proceed to appropriate treatment.

- The purpose of impedance pH monitoring in adults is to diagnosis achalesia and inform a decision whether to proceed to appropriate treatment.

Populations
The relevant population of interest is individuals with GERD.

The relevant population of interest is adults with achalasia.

The relevant population of interest is children and adolescents ≤ 21 years of age for the evaluation of extraesophageal symptoms (laryngitis, pharyngitis, chronic cough) with symptoms similar to gastroesophageal reflux disease (GERD) to rule esophageal motility disorders.

Interventions
The test being considered is catheter-based pH monitoring and wireless pH monitoring.

The test being considered is impedance pH monitoring.

Comparators
- **Catheter – Based pH Monitoring:** The following practice is currently being used to manage GERD: standard of care.
- **Wireless pH Monitoring:** The following tests and practices are currently being used to manage GERD: catheter-based pH monitoring and standard of care.
- **Impedance pH Testing:**
  - The following tests and practices are currently being used to manage GERD: catheter-based pH monitoring and wireless pH monitoring and standard of care.
  - The following tests and practices are currently being used to diagnose achalasia or esophageal motility disorders 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.

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).

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 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.

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.

Catheter – Based pH Monitoring and Wireless pH Monitoring for Gastroesophageal Reflux Disease

Catheter-Based pH Monitoring for Gastroesophageal Reflux Disease (GERD)
There is no independent reference standard for gastroesophageal reflux disease (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, authors of a technical review, "to conclude 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 1 is better than the other.

No randomized controlled trials (RCTs) were identified that assessed the clinical utility of catheter-based pH testing for this population.

Section Summary
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. 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 (GERD)
A systematic review and meta-analysis by Kessels et al (2017) were 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 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 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.

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 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.

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. 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.

No randomized controlled trials (RCTs) were identified that assessed the clinical utility of wireless pH testing for this population.

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
For individuals who have gastroesophageal reflux disease (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 and there is a lack of benefit associated with this procedure.

Summary of Evidence - GERD
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 and there is a lack of benefit associated with this procedure.
For individuals who have gastroesophageal reflux disease (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 and there is a lack of benefit associated with this procedure.

Catheter – Based pH Monitoring and Wireless pH Monitoring for Other Indications
Based on the review of the peer reviewed medical literature and society guidelines including American College of Gastroenterology (ACG) the following indications are appropriate to perform catheter- based pH monitoring and wireless pH monitoring in children, adolescents, and adults who are able to report symptoms:

- Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical anti-reflux repair (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
- Evaluation of patients after anti-reflux surgery who are suspected to have ongoing abnormal reflux (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
- Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy (pH study after withholding antisecretory drug regimen for at least 1 week if the study is done to confirm excessive acid exposure or while taking the antisecretory drug regimen if the symptom-reflux correlation is to be scored); **or**
- To detect refractory reflux in patients with chest pain after cardiac evaluation and after a one-month trial of proton pump inhibitor therapy; **or**
- Evaluation of suspected otolaryngologic manifestations (i.e., laryngitis, pharyngitis, chronic cough) of gastroesophageal reflux disease (GERD) that have failed to respond to at least 4 weeks of proton pump inhibitor therapy; **or**
- To document concomitant ggastroesophageal reflux disease (GERD) in an individual with adult-onset, non-allergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding antisecretory drugs for at least 1 week).

Based on the review of the peer reviewed medical literature for infants or children who are unable to report or describe symptoms of reflux for any of the following indications:

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

The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcomes.

Esophageal Impedance pH Testing

Impedance pH Testing for Gastroesophageal Reflux Disease (GERD)

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.

An observational cohort study by Gyawali et al (2021) reported that abnormal impedance pH testing while patients with proven gastroesophageal reflux disease (GERD) were taking twice daily PPIs was associated with lack of response to acid-suppression therapy.

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 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

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.

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.

Summary of Evidence-GERD

For individuals who have gastroesophageal reflux disease (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 there is a lack of benefit associated with this procedure. Based on society guidelines on the clinical use of physiologic testing the use of pH impedance monitoring for the diagnosis of GERD is low quality of evidence.

Impedance pH Testing in Children and Adolescents and Symptoms Similar to GERD to Rule-Out Esophageal Motility Disorders

The purpose of impedance pH monitoring in children and adolescents to evaluate for gastroesophageal reflux disease (GERD) is to inform a decision whether to proceed to appropriate treatment. Based on the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) working group high- resolution manometry (HRM) in the evaluation of extraesophageal symptoms HRM with impedance can rule out esophageal motility disorders whose presenting symptoms are often similar to GERD. HRM with impedance cannot only detect abnormalities of peristalsis and esophageal outlet obstruction but also associated abnormalities in bolus transit. Esophageal stasis puts patients at high risk for aspiration, not from reflux but due to the retained fluid secondary to the dysmotility or obstruction, with signs and symptoms often being similar to GERD. This is based on a strong recommendation. The evidence is sufficient to determine the technology improves net health outcomes.

For all other indications to include using manometry for the diagnosis of GERD and infants and children based on the peer review medical literature, there is low quality evidence. There are no studies of clinical utility showing improved outcomes, and the chain of evidence supporting the utility of the test is weak and shows a lack of benefit associated with this testing.

Impedance pH Testing for Achalasia

Achalasia is an incurable disease, and the underlying etiology remains unknown. The primary etiology of achalasia is believed to be selective loss of inhibitory neurons in the myenteric plexus of the distal esophagus and lower esophageal sphincter (LES), resulting in a neuronal imbalance of excitatory and inhibitory activity. Excitatory neurons release acetylcholine, whereas inhibitory neurons primarily release vasoactive intestinal peptide and nitric oxide. A localized decrease of vasoactive intestinal peptide and nitric oxide with unopposed excitatory activity causes failure of LES relaxation and disruption of esophageal peristalsis.

Per UpToDate regarding achalasia, pathogenesis, clinical manifestations, and diagnosis; both conventional and high-resolution manometry (HRM) can diagnose achalasia, but HRM is preferred. HRM may have a higher sensitivity in diagnosing achalasia as compared with conventional manometry, as it provides enhanced detail in the characterization of achalasia and the morphology of the esophagogastric junction. HRM can also be used to accurately categorize achalasia into one of three distinctive subtypes, which can guide prognosis and management. Conventional manometry cannot reliably identify type II and III achalasia, an important distinction as prognostic and therapeutic implications for these entities are different.

An incorrect gastroesophageal reflux disease (GERD) diagnosis often leads to a significant delay in achalasia diagnosis until patients have persistent symptoms that eventually lead to the correct diagnostic studies. The purpose of impedance pH

monitoring in adults is to diagnosis achalasia and inform a decision whether to proceed to appropriate treatment. Based on the 2020 American College of Gastroenterology guideline regarding the diagnosis and management of achalasia the diagnosis of achalasia is confirmed through high-resolution manometry (HRM) (includes pH monitoring and pH impedance testing) which is the current gold standard test. HRM leverages improved space-time resolution and a more intuitive description of contractile and pressure patterns to refine the classification of motor dysfunction that was originally described using conventional low-resolution pressure patterns to refine the classification of motor dysfunction that was originally described using conventional low-resolution pressure tracing manometry. The main benefits of this classification are an improved accuracy, an ability to distinguish clinically relevant subtypes, and a higher level of reproducibility. Correct diagnosis, treatment, and management of patients with achalasia is crucial to ensure optimal patient management. The evidence is sufficient to determine the technology improves net health outcomes.

For all other indications based on the peer review medical literature, there is low quality evidence. There are no studies of clinical utility showing improved outcomes, and the chain of evidence supporting the utility of the test is weak and shows a lack of benefit associated with this procedure.

Practice Guideline and Position Statements

American College of Gastroenterology (ACG)
In 2022, the American College of Gastroenterology (ACG) issued a guideline on the diagnosis and management of gastroesophageal reflux disease which includes the following recommendations:

Recommendations for the Diagnosis of GERD

- For patients with classic GERD symptoms of heartburn and regurgitation who have no alarm symptoms, we recommend an 8-week trial of empiric PPIs once daily before a meal (Strong recommendation, moderate level of evidence).
- We recommend attempting to discontinue the PPIs in patients whose classic GERD symptoms respond to an 8-week empiric trial of PPIs (Conditional recommendation, low level of evidence).
- We recommend diagnostic endoscopy, ideally after PPIs are stopped for 2-4 weeks, in patients whose classic GERD symptoms do not respond adequately to an 8-week empiric trial of PPIs or who symptoms return when PPIs are discontinued (Strong recommendation, low level of evidence)
- 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).
- We do not recommend the use of barium swallow solely as a diagnostic test for GERD (Conditional recommendation, low level of evidence).

- We recommend endoscopy as the first test for evaluation of patients presenting with dysphagia or other alarm symptoms (weight loss and GI bleeding) and for patients with multiple risk factors for Barrett's esophagus (Strong recommendation, low level of evidence).
- In patients for whom the diagnosis of GERD is suspected but not clear, and the endoscopy shows no objective evidence of GERD, we recommend reflux monitoring be performed off therapy to establish 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).

Key Concept
We do not recommend high-resolution manometry (HRM solely as a diagnostic test for GERD.

In 2021, the American College of Gastroenterology (ACG) issued a guideline on the clinical use of physiologic testing which includes the following recommendations:

- We recommend that patients with obstructive esophageal symptoms without a mechanical cause undergo high-resolution esophageal manometry for the evaluation for esophageal motility disorders (conditional recommendation, very low quality of evidence).
- We recommend HRM over conventional line tracing manometry for the diagnosis of esophageal motility disorders in patients with obstructive esophageal symptoms (strong recommendation, moderate quality of evidence).
- We recommend the utilization of supplementary/provocative maneuvers with the manometry protocol to improve the diagnostic yield of esophageal motility disorders in patients with obstructive esophageal symptoms (conditional recommendation, low quality of evidence).
- We recommend inclusion of a barium tablet with a barium esophagram during the evaluation of obstructive esophageal symptoms (conditional recommendation, very low quality of evidence).
- We recommend the use of ambulatory reflux monitoring over patient-reported symptoms on GERD questionnaires for a conclusive diagnosis of GERD in patients with esophageal reflux symptoms (conditional recommendation, very low quality of evidence).
- We recommend the use of ambulatory reflux monitoring over the assessment of response to PPI therapy for a conclusive diagnosis of GERD in patients with esophageal reflux symptoms (conditional recommendation, very low quality of evidence).
- We recommend the use of ambulatory reflux monitoring over upper endoscopy alone (if endoscopy is not definitive) for a conclusive diagnosis of GERD in patients with esophageal reflux symptoms not responding to PPI (conditional recommendation, very low quality of evidence).

- We recommend the use of ambulatory reflux monitoring performed off antisecretory therapy over ambulatory reflux monitoring on antisecretory therapy for a conclusive diagnosis of GERD in patients with typical reflux symptoms and unproven GERD (conditional recommendation, low quality of evidence).
- We recommend the use of prolonged wireless pH monitoring over 24-hour catheter-based monitoring for the diagnosis of GERD in adults with infrequent symptoms or day-to-day variation in esophageal symptoms (conditional recommendation, very low quality of evidence).
- We recommend the use of ambulatory pH impedance monitoring on 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 (proven GERD) (conditional recommendation, very low quality of evidence).
- We recommend that for patients with esophageal symptoms being evaluated for antireflux surgery, abnormal AET be considered a predictor of treatment outcome; RSA and mean nocturnal BI provide adjunctive value (conditional recommendation, very low quality of evidence).
- We recommend that the EGJ and gastric cardia anatomy should be inspected endoscopically and/or radiographically to assess mechanical abnormalities in patients with esophageal symptoms after ARS (conditional recommendation, very low quality of evidence).
- We recommend ambulatory reflux monitoring, specifically pH impedance monitoring performed off acid suppression, over laryngoscopy for a diagnosis of extraesophageal reflux (strong recommendation, low quality of evidence).
- We recommend up-front ambulatory reflux monitoring off acid suppression over an empiric trial of PPI therapy for extraesophageal reflux symptoms without concurrent typical reflux symptoms (conditional recommendation, very low quality of evidence).
- We recommend HRIM with postprandial monitoring be used to confirm the diagnosis of rumination if clinically necessary in patients with esophageal symptoms suspicious for rumination syndrome (conditional recommendation, low quality of evidence).
- We recommend that for patients with excessive belching, pH impedance monitoring can be used to confirm the diagnosis of supragastric belching (conditional recommendation, very low quality of evidence).

In 2020, the American College of Gastroenterology (ACG) issued a guideline on the diagnosis and management of achalasia which includes the following recommendations:

- We recommend that patients who are initially suspected of having GERD but do not respond to acid-suppressive therapy should be evaluated for achalasia.
- The diagnosis of achalasia is confirmed with high-resolution manometry (HRM), which is the current gold standard test.

American Gastroenterology Association
In 2011, the AGA's medical position statement on the management of Barrett's esophagus noted that "The guideline developers recommend against attempts to eliminate esophageal acid exposure (proton pump inhibitors [PPIs] in doses greater than once daily, esophageal pH monitoring to titrate PPI dosing, or anti-reflux surgery) for the prevention of esophageal adenocarcinoma (strong recommendation, moderate-quality evidence)".

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

Esophageal manometry is recommended for preoperative evaluation but has no role in the diagnosis of GERD. (Strong recommendation, low level of evidence)

Ambulatory esophageal reflux monitoring is indicated before consideration of endoscopic or surgical therapy in patients with non-erosive disease, as part of the evaluation of patient’s refractory to PPI therapy, and in situations when the diagnosis of GERD is in question. (Strong recommendation, low level of evidence).

Ambulatory reflux monitoring is the only test that can assess reflux symptom association. (Strong recommendation, low level of evidence)

Ambulatory reflux monitoring is not required in the presence of short or long-segment Barrett’s esophagus to establish a diagnosis of GERD. (Strong recommendation, moderate level of evidence)

Clinical Practice Update Committee of the AGA Institute
The functional luminal imaging probe is a Food and Drug Administration–approved measurement tool used to measure simultaneous pressure and diameter to guide management of various upper gastrointestinal disorders. Additionally, this tool is also approved to guide therapy during bariatric procedures and specialized esophageal surgery. Although it has been commercially available since 2009 as the endolumenal functional lumen imaging probe (EndoFLIP), the functional luminal imaging probe has had limited penetrance into clinical settings outside of specialized centers. This is primarily because of a paucity of data supporting its utility in general practice and a lack of standardized protocols and data analysis methodology. However, data are accumulating that are providing guidance regarding emerging applications in the evaluation and management of foregut disorders. This clinical practice update describes

the technique and reviews potential indications in achalasia, eosinophilic esophagitis, and gastroesophageal reflux disease.

Best Practice Advice 1: Clinicians should not make a diagnosis or treatment decision based on functional lumen imaging probe (FLIP) assessment alone.

Best Practice Advice 2: FLIP assessment is a complementary tool to assess esophagogastric junction opening dynamics and the stiffness of the esophageal wall.

Best Practice Advice 3: Utilization should follow distinct protocols and analysis paradigms based on the disease state of interest.

Best Practice Advice 4: Clinicians should not utilize FLIP in routine diagnostic assessments of gastroesophageal reflux disease.

Best Practice Advice 5: FLIP should not be used to diagnose eosinophilic esophagitis but may have a role in severity assessment and therapeutic monitoring.

International Consensus on Assessment of Oropharyngeal Dysphagia
In 2017, the International Consensus on Assessment of Oropharyngeal Dysphagia consensus assessment on oropharyngeal dysphagia states the following: In terms of objective investigations for OD, there are 5 main exams cited in the literature (functional endoscopic evaluation of swallowing (FEES), video fluoroscopic swallowing study (VFSS), esophageal manometry, pharyngeal pH monitoring, esophageal impedance pH monitoring). FEES and VFSS are considered the 2 most informative exams, allowing the identification of patients at risk for aspiration pneumonia. FEES is more practical to perform in the clinical setting given that the only material requirement is a fiberoptic laryngoscope.

Recommendation 1: for the objective investigation of OD, it is recommended to systematically perform either a FEES or VFSS, FEES being the preferred initial investigation given its increased ease of use.

There is no further mention or recommendation of the use of impedance monitoring in the assessment of dysphagia.

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)
In 2018, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) issued an update to their pediatric gastroesophageal reflux clinical practice guideline that includes the following recommendations:

HRM with impedance can rule out esophageal motility disorders whose presenting symptoms are often similar to GERD. This is considered gold standard for evaluation of esophageal motility disorders.

HRM in the evaluation of extraesophageal symptoms HRM with impedance can rule out esophageal motility disorders whose presenting symptoms are often similar to GERD. HRM with impedance can not only detect abnormalities of peristalsis and esophageal outlet obstruction but also associated abnormalities in bolus transit.
Esophageal stasis puts patients at high risk for aspiration, not from reflux but due to the retained fluid secondary to the dysmotility or obstruction, with signs and symptoms often being similar to GERD. Manometry can also be paired with pH-MII in 24-hour reflux studies to improve the cough-reflux correlation; manometrically coughs appear as high pressure, simultaneous pressure spikes on the pH-MII tracing. The accuracy of the device is increased by the fact that every cough-reflux pair can be detected.

Recommendations:

- Based on expert opinion, the working group suggests not to use manometry for the diagnosis of GERD in infants and children (Strong recommendation).
- Based on expert opinion the working group suggests to consider use of manometry when a motility disorder is suspected (Strong recommendation).

Society of American Gastrointestinal and Endoscopic Surgeons
In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guidelines states the following: “Ambulatory reflux monitoring is not required in the presence of short or long-segment Barrett’s esophagus to establish a diagnosis of GERD.” (Strong recommendation, moderate level of evidence).

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

Several wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared for marketing by FDA through the 510(k) process. Examples include the Bravo™ pH Monitoring System (Medtronic, now Given Imaging) was cleared for marketing by FDA through the 510(k) process for the purpose of “gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.”, the Sandhill Scientific PediaTec™ pH Probe (Sandhill Scientific), the ORION II Ambulatory pH Recorder (MMS, Medical Measurement Systems), and the TRIP CIC Catheter (Tonometrics).

PRIOR APPROVAL

Not applicable.

POLICY

Esophageal pH Monitoring using a Catheter-Based System or Catheter-Free, Wireless Esophageal Monitoring

Esophageal pH monitoring (91034/91035) using a catheter-based system or catheter-free, wireless esophageal monitoring may be considered **medically necessary** for any of the following indications in children, adolescents, and adults able to report symptoms:

- Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical anti-reflux repair (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
- Evaluation of patients after antireflux surgery who are suspected to have ongoing abnormal reflux (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
- Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy (pH study after withholding antisecretory drug regimen for at least 1 week if the study is done to confirm excessive acid exposure or while taking the antisecretory drug regimen if the symptom-reflux correlation is to be scored); **or**
- To detect refractory reflux in patients with chest pain after cardiac evaluation and after a one-month trial of proton pump inhibitor therapy; **or**
- Evaluation of suspected otolaryngologic manifestations (i.e., laryngitis, pharyngitis, chronic cough) of gastroesophageal reflux disease (GERD) that have failed to respond to at least 4 weeks of proton pump inhibitor therapy; **or**
- To document concomitant gastroesophageal reflux disease (GERD) in an individual with adult-onset, non-allergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding antisecretory drugs for at least 1 week).

24-hour catheter-based esophageal pH monitoring (91034/91035) may be considered **medically necessary** in infants or children who are unable to report or describe symptoms of reflux for any of the following indications:

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

Non-catheter based (i.e., wireless) the Bravo pH Monitoring System is considered **investigational** for evaluation in those under 4 years old for any indication, because it has not been FDA approved for use in this age group.

Esophageal pH monitoring is **not medically necessary** for all other indications, including, but not limited to the following:

- To detect or verify reflux esophagitis; **or**
- To verify gastroesophageal reflux disease (GERD) with Barrett's esophagus; **or**
- To evaluate "alkaline reflux"; **or**
- To titrate PPI dosing or manage patients that have already been diagnosed with gastroesophageal reflux disease (GERD); **or**
- To titrate PPI dosing in the management of Barrett's esophagus; **or**
- As routine work-up of an individual with symptoms of gastroesophageal reflux disease (GERD).

Impedance pH Monitoring (Multichannel Intraluminal Impedance) (91037/91038)
High-resolution manometry (HRM) (includes catheter- based impedance pH monitoring) may be considered **medically necessary** for the evaluation of extraesophageal symptoms (laryngitis, pharyngitis, chronic cough) with symptoms similar to gastroesophageal reflux disease (GERD) in children and adolescents ≤ 21 years of age to rule out esophageal motility disorders.

High-resolution manometry (HRM) (includes catheter- based impedance pH monitoring) is considered **not medically necessary** in children and adolescents ≤ 21 years of age when the above criteria is not met and for all other indications due to lack of benefits associated with this procedure.

High-resolution manometry (HRM) (includes catheter- based impedance pH monitoring) is considered **medically necessary** in adults for the diagnosis of achalasia.

High – resolution manometry (HRM) (includes catheter- based impedance pH monitoring) in adults is considered **not medically necessary** when the above criteria is not met and for all other indications due to lack of benefits associated with this procedure.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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)

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POLICY HISTORY		
Date	**Reason**	**Action**
September 2022	Annual Review	Policy Revised
September 2021	Annual Review	Policy Revised
September 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Revised
September 2018	Annual Review	Policy Revised
September 2017	Annual Review	Policy Revised
September 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised

January 2014	Annual Review	Policy Revised
October 2013	Interim Review	Policy Renewed
February 2013	Annual Review	Policy Renewed
February 2012	Annual Review	Policy Revised
April 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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