2.01.20	Esophageal pH Monitoring		
Original Policy Date:	January 1, 1990	**Effective Date:**	January 1, 2022
Section:	2.0 Medicine	**Page:**	Page 1 of 18

Policy Statement

Esophageal pH monitoring using a catheter or wireless-based system may be considered **medically necessary** for **any** of the following clinical indications in adults and children or adolescents able to report symptoms*:

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

I. Unexplained apnea
II. Bradycardia
III. Refractory coughing or wheezing, stridor, or recurrent choking (aspiration)
IV. Persistent or recurrent laryngitis
V. Recurrent pneumonia

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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The above medically necessary indications are in accordance with the policy guidelines and 2020 American College of Gastroenterology clinical guideline on the clinical use of esophageal physiologic testing (see Supplemental Information).

***Note:** Esophageal pH monitoring systems should be used in accordance with U.S. Food and Drug Administration-approved indications and age ranges.

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

Coding

Catheter-Free, Wireless Recording:

- **91035**: Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Note: The device may be placed with either endoscopic or manometry guidance.

Catheter-Based Monitoring:

- **91034**: Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation

Catheter-based Impedance-pH Monitoring (to test esophageal function):

- **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)

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).

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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. A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System; Medtronic, now Given Imaging) was cleared for marketing by the 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."

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 (Given Imaging), 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.

Rationale

Background

Gastroesophageal Reflux Disease

Acid reflux is the cause of heartburn and acid regurgitation esophagitis, which can lead to esophageal stricture. Acid reflux can also cause or contribute to some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis, subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia.

Diagnosis

Gastroesophageal reflux disease is most commonly diagnosed by clinical evaluation and treated empirically with a trial of medical management. For patients who do not respond appropriately to medications, or who have recurrent chronic symptoms, endoscopy is indicated to confirm the diagnosis and assess the severity of reflux esophagitis. In some patients, endoscopy is nondiagnostic, or results are discordant with the clinical evaluation (in these cases, further diagnostic testing may be of benefit).

Monitoring

Esophageal monitoring is done using a tube with a pH electrode attached to its tip, which is then passed into the esophagus to approximately 5 cm above the upper margin of the lower esophageal sphincter. The electrode is attached to a data recorder worn on a waist belt or shoulder strap. Every instance of acid reflux, as well as its duration and pH, is recorded over a 24-hour period. Wireless pH monitoring is achieved using endoscopic or manometric guidance to attach the pH measuring capsule to the esophageal mucosa using a clip. The capsule records pH levels for up to 96 hours and transmits them via radiofrequency telemetry to a receiver worn on the patient's belt. Data from the recorder are uploaded to a computer for analysis by a nurse or doctor.

Another technology closely related to pH monitoring is impedance pH monitoring, which incorporates pH monitoring with measurements of impedance, a method of measuring reflux of liquid or gas of any pH. Multiple electrodes are placed along the length of the esophageal catheter. The impedance pattern detected can determine the direction of flow and the substance (liquid or gas). Impedance monitoring can identify reflux events in which the liquid is only slightly acidic or nonacidic.

Literature Review

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

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

Catheter-Based pH Monitoring for Gastroesophageal Reflux Disease

Clinical Context and Test Purpose

The purpose of catheter-based pH monitoring in patients who have gastroesophageal reflux disease (GERD) is to inform a decision whether to proceed to appropriate treatment.

The question addressed in this evidence review is: Does the use of catheter-based pH monitoring improve the net health outcome in individuals with GERD?

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

Populations
The relevant population of interest is individuals with GERD.

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

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

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

Study Selection Criteria
For the evaluation of clinical validity of the tests in this review, studies that meet the following eligibility criteria were considered:

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

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

Review of Evidence
There is no independent reference standard for GERD for specific populations. Traditional pH monitoring has been evaluated in patients with endoscopically diagnosed GERD, where it has been shown to be positive 77% to 100% of the time.[1.] However, in clinically defined but endoscopically negative patients, the test is positive from 0% to 71% of the time. In normal control populations, traditional pH monitoring is positive in 0% to 15% of subjects. Thus, the test is imperfectly sensitive and specific in patients with known presence or absence of disease. The current evidence 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 1 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 patients who have GERD is to inform a decision whether to proceed to appropriate treatment.

The question addressed in this evidence review is: Does the use of wireless pH monitoring improve the net health outcome in individuals with GERD?

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

Populations
The relevant population of interest is individuals with GERD.

Interventions
The test being considered is wireless pH monitoring.

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

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

Study Selection Criteria
For the evaluation of clinical validity of the tests in this review, studies that meet the following eligibility criteria were considered:

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

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

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

Cohort Studies
Studies published since the 2006 TEC Special Report have shown similar findings on the correlation between wireless pH monitoring and standard catheter monitoring. Hakanson et al (2009) evaluated simultaneous wireless and traditional pH testing in 92 patients.[4] Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The 2 techniques correlated (r^2=0.66); however, the range between limits of agreement was wide. The techniques were concordant on the final diagnosis 82.1% of the time. Wenner et al (2007), in 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%.[5] The sensitivity of wireless monitoring was noted to be worse than other studies of traditional pH monitoring, but the patient population may have had less severe disease. A study by Schneider et al (2007) revealed a similar diagnostic performance of wireless and traditional pH monitoring.[6]

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.[7] In this particular study, comparison of outcomes for patients who received wireless monitoring, and a matched control group who received traditional catheter monitoring, showed similar outcomes and satisfaction. Sweis et al (2011) assessed wireless pH monitoring up to 96 hours in 38 patients with ongoing GERD symptoms who failed 24-hour catheter-based pH monitoring.[8] The results revealed an objective GERD diagnosis in 37% of patients at 96 hours. The authors concluded that prolonged wireless pH-monitoring increases sensitivity and diagnostic yield in patients experiencing esophageal symptoms despite negative 24-hour catheter-based pH testing, but the results should not be applied to all patients with negative catheter-based pH monitoring. Garrean et al (2008) studied the use of 96-hour pH testing where, during the first 2 days of monitoring, patients were off therapy, and during the second 2 days, they were prescribed PPIs.[9] As expected, during the second and third days, fewer patients showed reflux symptoms. It is difficult to determine from data analysis how such a testing protocol improves the diagnosis of GERD. Scarpulla et al (2007) attempted 96-hour monitoring in 83 patients.[10] Monitoring for the full 96 hours was successful in 41% of patients. In them, the proportion showing some degree of pathologic acid exposure increased as monitoring time increased.

Some studies have attempted to support an argument that a longer monitoring time with a wireless monitor would result in a superior test performance; however, without a reference standard, or showing superior patient outcomes based on the longer test, such an argument cannot be made. The longer monitoring period usually results in a larger proportion of tests that are classified as positive, depending on the method of determining a positive test. Prakash and

Clouse (2005) compared the diagnostic yield for a single day of monitoring with the complete 2 days of monitoring.[11] 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 patients who have GERD is to inform a decision whether to proceed to appropriate treatment.

The question addressed in this evidence review is: Does the use of impedance pH testing improve the net health outcome in individuals with GERD?

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

Populations
The relevant population of interest is individuals with GERD.

Interventions
The test being considered is impedance pH testing.

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

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

Study Selection Criteria
For the evaluation of clinical validity of the tests in this review, studies that meet the following eligibility criteria were considered:

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

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

Review of Evidence
Evidence on the use of impedance pH testing suffers from issues similar to the evaluation of wireless pH testing: lack of a reference standard and lack of evidence that shows improved patient outcomes. Many studies have argued that an increase in positive tests, or diagnostic yield, is by itself evidence that supports the validity of the test. However, the increase in positive tests, if it indicates increased sensitivity, may decrease specificity. The net effect on patient management and patient outcomes is uncertain.

Several studies have demonstrated a higher yield for positive tests when using impedance pH testing and identifying reflux events that are nonacidic or only weakly acidic (and thus would not be detected using pH testing alone).[12,13,14] For example, Bajbouj et al (2007) studied 41 patients with atypical GERD symptoms with numerous tests.[12] The test producing the highest number of positive findings was impedance pH testing. Bredenoord et al (2006) did a similar study in 48 patients.[13] 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.[14]

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.[15] 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.[16]

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 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.

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers for 2010. Input was mixed. Most reviewers indicated that the wireless device was more comfortable and allowed patients to do more varied activities during the recording. One reviewer cited problems with availability of the catheter-based systems. Moreover, most reviewers agreed that a link between wireless monitoring and improved health outcome had not been demonstrated.

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

American College of Gastroenterology
In 2020, the American College of Gastroenterology (ACG) released a clinical guideline on the clinical use of esophageal physiologic testing.[17] 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).

In 2013, ACG published guidelines on the diagnosis and management of GERD.[18] The guidelines stated, "ambulatory esophageal reflux monitoring is indicated before consideration of endoscopic or surgical therapy in patients with nonerosive 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 ACG guidelines noted there was limited evidence and lack of clear consensus on how testing should be performed (e.g., catheter-based pH, wireless pH, or impedance pH) for refractory GERD.

American Gastroenterological Association
In 2008, the American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD.[19] Ambulatory impedance

pH, catheter pH, and wireless pH monitoring were all supported as methods to evaluate patients with suspected GERD with otherwise normal endoscopy and no response to PPI therapy. The guidelines had a grade B recommendation, denoting fair evidence that in practice improves health outcomes. The guidelines additionally stated that the wireless pH monitor had superior sensitivity to catheter pH monitoring because of the extended period of recording.

However, as noted previously, an increase in positive tests has been documented in other reports as producing both increased sensitivity and decreased specificity relative to the reference standard used in the particular study. Thus, taking into account both characteristics of diagnostic performance, it is unclear whether patient outcomes are improved.

In 2017, the American Gastroenterological Association authored a white paper that discussed strategies to define and diagnose GERD.[20] The paper provided narrative comments on esophageal pH testing methods but did not provide any recommendations regarding their appropriate use.

The Lyon Consensus

In 2018, an expert panel known as the Lyon Consensus provided GERD diagnosis recommendations that updated a prior consensus (the 2002 Porto consensus, published in 2004) and incorporated several prior consensus statements including Roman et al 2017 and Savarino et al 2017 (both summarized below).[21] The Lyon Consensus proposed that esophageal pH monitoring always be performed after stopping PPI therapy in patients with unproven GERD (no esophagitis on endoscopy and no prior pH testing). In this case, the monitoring modality (i.e., catheter, wireless, or impedance) can be chosen based on availability and cost.

Patients with proven GERD (i.e., esophagitis, Barrett's esophagus, or prior abnormal pH testing) who do not respond to initial therapy should undergo impedance pH monitoring while taking double-dose PPI therapy. These patients should also undergo endoscopy and high-resolution manometry.

The consensus document stated that the most helpful assessment metric from pH monitoring is the acid exposure time due to its reproducibility and data suggesting that it can predict response to medical and surgical antireflux therapy. An acid exposure time >6% is considered conclusive evidence for the presence of acid reflux. The number of reflux episodes is an adjunctive assessment metric that can be used when the acid exposure time is inconclusive for diagnosing GERD.

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.[22] 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.[23] 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.

Esophageal Diagnostic Working Group
In 2013, an esophageal diagnostic working group published a guidance document on appropriate use of wireless pH monitoring in patients with GERD.[24] Recommendations for impedance pH testing were not provided due to limited data that it improves GERD outcomes. For patients whose GERD symptoms have not responded to optimized PPI therapy and who do not have a confirmed diagnosis of acid reflux, either prolonged wireless pH monitoring or catheter monitoring for 24 hours is recommended. These tests should be performed after patients have stopped PPI therapy. If the initial test suggests a high likelihood of GERD but the patient does not respond to escalated acid suppressive therapy, impedance pH monitoring for 24 hours while receiving a PPI is recommended. For patients who are referred for an antireflux procedure who do not have a confirmed diagnosis of acid reflux, either prolonged wireless pH monitoring or catheter monitoring for 24 hours is appropriate (PPI therapy should be held before the procedure).

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
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.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in October202 1 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Diagnoses and symptoms
  - Reason for procedure
  - Prior treatment and response
- Endoscopy report(s) (if applicable)
- Imaging reports

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
01/01/1990	New Policy Adoption
06/01/1999	Policy revision with position change
04/02/2010	Policy revision with position change
06/28/2013	Policy revision with position change
07/31/2015	Coding update
02/01/2016	Policy revision without position change
02/01/2017	Policy revision without position change
01/01/2018	Policy revision without position change
02/01/2019	Policy revision without position change
01/01/2020	Annual review. No change to policy statement. Literature review updated.
01/01/2021	Annual review. No change to policy statement. Literature review updated.
01/01/2022	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Esophageal pH Monitoring 2.01.20 **Policy Statement:** Esophageal pH monitoring using a catheter or wireless-based system may be considered **medically necessary** for **any** of the following clinical indications in adults and children or adolescents able to report symptoms*: I. Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical antireflux repair II. Evaluation of patients after antireflux surgery who are suspected of having ongoing abnormal reflux III. Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms refractory to proton pump inhibitor (PPI) therapy IV. Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a 1-month trial of proton pump inhibitor therapy V. Evaluation of suspected otolaryngologic manifestations of gastroesophageal reflux disease (GERD) (i.e., laryngitis, pharyngitis, chronic cough) in patient who have failed to respond to at least 4 weeks of proton pump inhibitor therapy VI. Evaluation of concomitant gastroesophageal reflux disease in patients 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 **any** of the following symptoms: I. Unexplained apnea II. Bradycardia III. Refractory coughing or wheezing, stridor, or recurrent choking (aspiration) IV. Persistent or recurrent laryngitis V. Recurrent pneumonia	**Esophageal pH Monitoring 2.01.20** **Policy Statement:** Esophageal pH monitoring using a catheter or wireless-based system may be considered **medically necessary** for **any** of the following clinical indications in adults and children or adolescents able to report symptoms*: I. Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical antireflux repair II. Evaluation of patients after antireflux surgery who are suspected of having ongoing abnormal reflux III. Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms refractory to proton pump inhibitor (PPI) therapy IV. Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a 1-month trial of proton pump inhibitor therapy V. Evaluation of suspected otolaryngologic manifestations of gastroesophageal reflux disease (GERD) (i.e., laryngitis, pharyngitis, chronic cough) in patient who have failed to respond to at least 4 weeks of proton pump inhibitor therapy VI. Evaluation of concomitant gastroesophageal reflux disease in patients 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 **any** of the following symptoms: I. Unexplained apnea II. Bradycardia III. Refractory coughing or wheezing, stridor, or recurrent choking (aspiration) IV. Persistent or recurrent laryngitis V. Recurrent pneumonia

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Catheter-based impedance pH monitoring is considered **not medically necessary**.	Catheter-based impedance pH monitoring is considered **not medically necessary**.