I. POLICY

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

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

* Esophageal pH monitoring systems should be used in accordance with FDA-approved indications and age ranges.

24-hour esophageal pH monitoring (standard catheter-based) may be considered medically necessary in infants or children who are unable to report or describe symptoms of reflux with, any of the following:

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

**Impedance–pH Monitoring**

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

**Cross-references:**

MP-2.053 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease  
MP-5.033 Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon

### II. **PRODUCT VARIATIONS**

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  
BlueJourney PPO*  
FEP PPO**

* Refer to the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 100.3, 24-Hour Ambulatory Esophageal pH Monitoring. Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

**Refer to FEP Medical Policy Manual MP-2.01.20 Esophageal pH Monitoring. The FEP Medical Policy Manual can be found at: www.fepblue.org

### III. **DESCRIPTION/BACKGROUND**

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of one to several days. These devices may aid in the diagnosis of gastroesophageal reflux disease (GERD) in patients who have an uncertain diagnosis after clinical evaluation and endoscopy.

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

Gastroesophageal reflux disease (GERD) 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 non-diagnostic, or results are discordant with the clinical evaluation. In these cases, further diagnostic testing may be of benefit.

Esophageal monitoring is done through the use of a tube with a pH electrode attached to its tip, which is then passed to almost exactly 5 cm above the upper margin of the lower esophageal sphincter (LES). The electrode is attached to a data logger worn on a waist belt or shoulder strap. Every instance of acid reflux, as well as its duration and pH, is recorded, indicating gastric acid reflux over a 24-hour period. A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System, Medtronic) has been cleared for marketing by the U.S. Food and Drug Administration (FDA) 510(k) process for the purpose of “gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.” Using endoscopic or manometric guidance, the capsule is temporarily implanted in 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 in 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 measurement 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 is able to identify reflux events in which the liquid is only slightly acidic or non-acidic.

**Regulatory Status**

Esophageal pH electrodes are FDA 510(k) exempt class I devices. A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System; Medtronic) has been cleared for marketing by the FDA 510(k) process for the purpose of “gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.”

A number of wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared through the 510(k) process. Some examples are 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.

**IV. RATIONALE**

The most recent literature review was performed for the period of April 28, 2015, through October 14, 2016. No new studies were identified in the latest literature review that would change our conclusions. A diagnostic test is generally evaluated by determining its analytic validity, its clinical validity (diagnostic test characteristics), and its clinical utility.
ANALYTIC VALIDITY
We did not identify any literature assessing the analytic validity of esophageal pH monitoring.

CLINICAL VALIDITY
Esophageal pH Monitoring Using Catheter-Based Systems
Esophageal pH monitoring for 24 hours using catheter-based systems is primarily used in patients with gastroesophageal reflux disease (GERD) that has not responded symptomatically to a program of medical therapy (including proton pump inhibitors [PPIs]) or in patients with refractory extra-esophageal symptoms. Although it is an established technology, aspects of its use as a diagnostic test for GERD are problematic and thus make it difficult to determine its utility, as well as the utility of potential alternative tests.

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 state of this evidence regarding the diagnostic capability of catheter-based pH monitoring led the authors of a technical review by Kahrilas et al “…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

Without a reference standard for GERD, it is difficult to compare the diagnostic test performance of different types of tests. It is possible to determine the degree to which 2 tests correlate with each other, but difficult to determine if one test is better than the other. Use of 1 test versus another may result in better patient outcomes if, despite being an imperfect test, differences in patient management based on the test results result in overall improved patient outcomes. However, this type of argument would require rigorous studies that follow patients beyond test outcome and are organized and analyzed such that a valid inference of improved outcome due to the use of the test can be made.

Wireless pH Monitoring
Several observations of relevance to this Policy are based on a 2006 TEC Special Report on wireless esophageal pH monitoring.2

Six case series reviewed in the report demonstrated success rates over 90% in achieving 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 as...
have been reported in such patients using traditional pH monitoring. Studies that directly compared the performance of traditional catheter and wireless pH monitoring in the same patients showed fairly close correlation between the 2 types of studies after correcting for calibration differences. However, the ideal cut-point for test positivity was different for the tests. Some studies attempted to support an argument that a longer monitoring time with a wireless monitor results in 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 compared the diagnostic yield for a single day of monitoring with the complete 2 days of monitoring.

They reported that the second day of recording time increased the proportion of subjects with symptoms by 6.8%. However, this study had several methodologic flaws. Ideally, a study that compares the diagnostic performance of an additional day of monitoring would require an independent reference standard or demonstration of improved patient outcomes when managing patients with a 1-day versus a 2-day study. In this study, the 2-day study was essentially considered the “reference test,” and there was no discussion of how the second day of monitoring was used to improve patient management in this heterogeneous group of patients. In addition, in their statistical analysis, the authors eliminated patients who did not report any symptoms during the testing period, thus deflating the denominator and inflating the yield of the additional day of testing. Finally, the 1-day test was essentially a component of the 2-day test, and thus the 2 monitoring periods were not independent, further limiting any comparison between them. A greater number of positive tests produced by a longer duration of test is not evidence of a superior test.

Studies published since the 2006 TEC Special Report show similar findings regarding the correlation of wireless pH monitoring and standard catheter monitoring. Wenner et al, 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%. This 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 showed similar diagnostic performance of wireless and traditional pH monitoring.

Hakanson et al evaluated simultaneous wireless and traditional pH testing in 92 patients. Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The 2 techniques were correlated ($r^2=0.66$); however, the range between limits of agreement was wide. The techniques were concordant regarding the final diagnosis 82.1% of the time.

Additional studies replicate findings that a longer period of monitoring increases the proportion of positive tests. Scarpulla et al attempted 96-hour monitoring in 83 patients. Monitoring for the full 96 hours was successful in 41% of patients. In these patients, the proportion showing some degree of pathologic acid exposure increased as the time of monitoring
increased. Garrean et al studied the use of 96-hour pH testing where during the first 2 days of monitoring, the patients were off therapy, and during the second 2 days, the patients were prescribed PPIs.8

As expected, during the second and third days, fewer patients showed reflux symptoms. It is difficult to determine from the analysis of data how such a testing protocol improves the diagnosis of GERD. Grigolon et al showed that in 51 patients receiving prolonged monitoring, the 96-hour test reduced the number of indeterminate tests from 11 to 5.9 In this particular study, comparison of outcomes of patients who received wireless monitoring and a matched control group of patients who received traditional catheter monitoring showed similar outcome and satisfaction.

**Impedance-pH Testing**

Evidence on the use of impedance-pH testing suffers from similar issues as the evaluation of wireless pH testing: lack of a reference standard, and lack of evidence that shows improved patient outcomes. Many studies use the argument 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 not certain.

Several studies have demonstrated a higher yield of positive tests when using impedance-pH testing and identifying reflux events that are non- or only weakly acidic (and thus would not be detected using pH testing alone).10-12

Bajbouj et al studied 41 patients with atypical GERD symptoms with numerous tests.10 The test that produced the highest number of positive findings was impedance-pH testing.

Bredenoord et al did a similar study in 48 patients.11 A higher proportion of subjects had positive tests when using impedance-pH data than when using pH data alone (77% vs 67%, respectively). A study by Mainie et al showed similar findings.12 Studies have examined the issue of performing impedance-pH testing while the patient is currently on acid suppression therapy. Vela et al demonstrated that during acid suppressive therapy, the total number of reflux episodes is similar, but fewer episodes of acidic reflux occur.13

Although impedance-pH testing produces a higher number of positive tests, particularly when compared with traditional or wired pH testing in the setting of concurrent acid suppressive therapy, there is not sufficient evidence that these test results are more accurate. nor is there a clear link to improved patient outcomes when using impedance-pH testing compared with other methods of measuring pH.
Clinical Validity: Section Summary
The tests under consideration all correlate with symptoms of GERD or endoscopically-defined GERD. However, without a true reference standard for clinical GERD, the diagnostic characteristics of catheter based pH monitoring, wireless pH monitoring, and impedance-pH testing are uncertain.

CLINICAL UTILITY
Clinical utility of pH testing can be determined by studies which directly compare strategies of diagnosis and treatment with pH testing compared to strategies of diagnosis and treatment without pH testing, or by a compelling indirect chain of evidence that supports improved outcomes with the use of pH testing. We did not identify studies evaluating the clinical utility of any of the tests. The indirect chain of evidence supporting its use has not been clearly formulated and argued.

SUMMARY OF EVIDENCE
For patients being evaluated for GERD who receive catheter-based pH monitoring, the evidence includes various cross-sectional studies in different populations evaluating test performance. Relevant outcomes include test accuracy, test validity, symptoms and functional outcomes. Positive pH monitoring tests correlate with endoscopically defined GERD and with GERD symptoms, but since 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 indirect chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

For patients being evaluated for GERD who receive wireless pH monitoring, the evidence includes various cross-sectional studies in different populations evaluating test performance and diagnostic yield. Relevant outcomes include test accuracy, test, validity, symptoms and functional outcomes. Positive wireless pH monitoring tests correlate with endoscopically defined GERD and with GERD symptoms, but since there is no reference standard for clinical GERD, diagnostic characteristics cannot be determined. Some studies show higher test positivity rates with prolonged wireless monitoring when compared to 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 indirect chain of evidence supporting the utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

For patients being evaluated for GERD who receive impedance pH testing, the evidence includes various cross-sectional studies in different populations evaluating test performance and diagnostic yield. Relevant outcomes include test accuracy, test validity, symptoms and functional outcomes. Positive impedance pH tests correlate with endoscopically defined GERD and with GERD symptoms, but since there is no reference standard for clinical GERD, diagnostic characteristics cannot be determined. Some studies show higher test positivity rates with impedance pH testing when compared to pH testing alone, but the effect of this finding on patient outcomes is uncertain. There are no studies of clinical utility showing improved outcomes.
outcomes, and the indirect chain of evidence supporting utility of the test is weak. The evidence is insufficient to determine that the technology improves health outcomes.

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, input was received from 1 physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review for 2010. The input was mixed. Most of the reviewers indicated that the wireless device was more comfortable and allowed patients to have more varied activities during the recording. One reviewer cited problems with availability of the catheter-based systems. Most agreed that a linkage between wireless monitoring and improved health outcome had not been demonstrated.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Gastroenterology

The American College of Gastroenterology (ACG) released practice guidelines on esophageal reflux testing in 2007. The literature up to 2006 was reviewed. Although the literature on wireless pH testing was extensively reviewed, the recommendations for testing made no distinction between wireless and traditional pH monitoring. An indirect endorsement of wireless monitoring might be inferred from a statement that says that a 48-hour study would produce a greater diagnostic yield from a symptom association test. Symptom-association tests require statistical testing of the data, and a 48-hour test produces more data points. However, apparently these statistical correlation tests are not perfect, as the guidelines state that such measures “do not ensure a response to either medical or surgical antireflux therapies.” No studies were cited in these guidelines that indicate superior outcomes for patients for treatment guided by wireless pH testing versus traditional pH testing. The major advantage for the wireless system cited was patient tolerability.

Impedance pH monitoring was cited as “may be useful” (a lower category of recommendation than for pH monitoring) for evaluation of patients with insufficient response to medical therapy in whom documentation of nonacid reflux would alter clinical management. It was suggested that impedance monitoring has a greater yield for findings than pH monitoring when performed on proton pump inhibitor (PPI) therapy. The last statement of the guideline states that implications of an abnormal impedance test are unproven at this time.

In 2013, ACG published guidelines on the diagnosis and management of GERD. The guidelines indicate “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 guidelines note there is 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**
The American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD in 2008.16 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 guideline is classified as a “grade B” recommendation, denoting fair evidence that the practice improves health outcomes. The guideline additionally states that the wireless pH monitor has 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 unknown as to whether patient outcomes are improved.

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence released technology appraisal guidance on catheterless esophageal pH monitoring in July 2006.17 This guidance indicates catheterless 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.

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**
Not applicable.

**MEDICARE NATIONAL COVERAGE**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**
A search of ClinicalTrials.gov in October 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

V. **DEFINITIONS**

**GASTROESOPHAGEAL REFLUX** is a backflow of contents of the stomach into the esophagus that is often the result of incompetence of the lower esophageal sphincter. Gastric juices are acid
and therefore produce burning pain in the esophagus. Repeated episodes of reflux may cause esophagitis, peptic esophageal stricture, or esophageal ulcer, also called GERD.

**SYMPTOM-REFLUX ASSOCIATION** indices have been developed to quantify the temporal association between symptoms and reflux episodes. The Symptom Index (SI) is defined as the percentage of symptoms that are associated with acid reflux events and the Symptom Sensitivity Index (SSI) as the percentage of acid reflux events that are associated with a symptom. Neither the SI, nor the SSI takes all factors involved (number of reflux episodes, number of symptom episodes, number of reflux-associated symptom episodes) into account. The Symptom Association Probability (SAP) index is currently considered to be the best tool for symptom association analysis. The SAP is based on statistical analysis (cross tabulation) of a contingency table consisting of four possible combinations of reflux and symptoms with the p value of <0.05 (Fisher’s exact test) proposed as its cut off point.

### VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

### VII. DISCLAIMER

*Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

*Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.*
### Medical Policy

**Policy Title**: Esophageal pH Monitoring  
**Policy Number**: MP-2.017

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IX. REFERENCES


Other:
Mosby’s Medical, Nursing, & Allied Health Dictionary 6th edition

X. POLICY HISTORY

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## Medical Policy

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unchanged. Changed statement regarding impedance pH monitoring from investigational to not medically necessary. FEP variation changed to refer to FEP policy manual.

**CAC 10/30/12** Changed statement to indicate wireless or catheter-based system may be used in esophageal pH monitoring. Deleted statement regarding 48- to 96-hour, catheter-free, wireless esophageal monitoring. Added statement indicating esophageal pH monitoring systems should be used in accordance with FDA approved indications and age ranges.

Codes reviewed 9/25/2012  
**CAC 11/26/13** Consensus.

**CAC 11/25/14** Consensus review. No change to the policy statements. References and rationale updated. Codes reviewed, no coding changes.

**CAC 11/24/15** Consensus review. No change to policy statements. References and rationale updated. Coding updated.

**Admin update 1/1/17:** Policy variations section updated.

**CAC 1/31/17** Consensus review. No change to the policy statements. References and rationale updated. Coding reviewed.

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**Top**