MEDICAL POLICY

POLICY TITLE	ESOPHAGEAL PH MONITORING
POLICY NUMBER	MP-2.017

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**12/11/2018**
Effective Date:	**2/1/2019**

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 gastroesophageal reflux disease (i.e., laryngitis, pharyngitis, chronic cough) in patients that have failed to respond to at least 4 weeks of proton pump inhibitor therapy;
- Evaluation of concomitant gastroesophageal reflux disease 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.

Twenty-four-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 Monitoring

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

Cross-references:

MP-2.053 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

MP-5.033 Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

II. PRODUCT VARIATIONS

TOP

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

III. DESCRIPTION/BACKGROUND

TOP

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of several days. Impedance pH monitoring measures electrical impedance in the esophagus to evaluate reflux episodes concurrent with changes in pH. These tests are used for certain clinical indications in the evaluation of gastroesophageal reflux disease (GERD).

GASTROESOPHAGEAL REFLUX DISEASE

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

Diagnosis

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

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

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

REGULATORY STATUS
Esophageal pH electrodes are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements. A catheter-free, temporarily implanted device (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."

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 (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

TOP

Summary of Evidence
For individuals who have GERD who receive catheter-based pH monitoring, the evidence includes various cross-sectional studies evaluating test performance in different populations. Relevant outcomes are test accuracy and 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 improves health outcomes.

For individuals who have GERD who receive wireless pH monitoring, the evidence includes various cross-sectional studies evaluating test performance and diagnostic yield in different populations. Relevant outcomes are test accuracy and 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 improves health outcomes.

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 accuracy and 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 improves health outcomes.

V. DEFINITIONS

TOP

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

TOP

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 BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross'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 BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

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.

Not medically necessary; therefore not covered:

CPT Codes®								
91037	91038							

Covered when medically necessary:

CPT Codes®								
91034	91035							

POLICY TITLE	ESOPHAGEAL pH MONITORING
POLICY NUMBER	MP-2.017

ICD-10-CM Diagnosis Codes	Description
J18.9	Pneumonia, unspecified organism
J31.2	Chronic pharyngitis
J37.0	Chronic laryngitis
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.991	Cough variant asthma
J45.998	Other asthma
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis
P24.80	Other neonatal aspiration without respiratory symptoms
P24.81	Other neonatal aspiration with respiratory symptoms
P28.4	Other apnea of newborn
P28.89	Other specified respiratory conditions of newborn
R00.1	Bradycardia, unspecified
R05	Cough
R06.1	Stridor
R06.2	Wheezing
R06.81	Apnea, not elsewhere classified
R07.89	Other chest pain

IX. REFERENCES

TOP

1. *Kahrilas PJ, Quigley EM. Clinical esophageal pH recording: a technical review for practice guideline development. Gastroenterology. Jun 1996;110(6):1982-1996. PMID 8964428*

2. *Kessels SJM, Newton SS, Morona JK, et al. Safety and efficacy of wireless pH monitoring in patients suspected of gastroesophageal reflux disease: a systematic review. J Clin Gastroenterol. Oct 2017;51(9):777-788. PMID 28877081*
3. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Wireless pH Monitoring. TEC Assessments. 2006;21(2).*
4. *Hakanson BS, Berggren P, Granqvist S, et al. Comparison of wireless 48-h (Bravo) versus traditional ambulatory 24-h esophageal pH monitoring. Scand J Gastroenterol. Dec 2009;44(3):276-283. PMID 19040176*
5. *Wenner J, Johansson J, Johnsson F, et al. Optimal thresholds and discriminatory power of 48-h wireless esophageal pH monitoring in the diagnosis of GERD. Am J Gastroenterol. Sep 2007;102(9):1862-1869. PMID 17509034*
6. *Schneider JH, Kramer KM, Konigsrainer A, et al. Ambulatory pH: monitoring with a wireless system. Surg Endosc. Nov 2007;21(11):2076-2080. PMID 17484003*
7. *Grigolon A, Consonni D, Bravi I, et al. Diagnostic yield of 96-h wireless pH monitoring and usefulness in patients' management. Scand J Gastroenterol. May 2011;46(5):522-530. PMID 21366495*
8. *Garrean CP, Zhang Q, Gonsalves N, et al. Acid reflux detection and symptom-reflux association using 4-day wireless pH recording combining 48-hour periods off and on PPI therapy. Am J Gastroenterol. Jul 2008;103(7):1631-1637. PMID 18557714*
9. *Scarpulla G, Camilleri S, Galante P, et al. The impact of prolonged pH measurements on the diagnosis of gastroesophageal reflux disease: 4-day wireless pH studies. Am J Gastroenterol. Dec 2007;102(12):2642-2647. PMID 17850412*
10. *Prakash C, Clouse RE. Value of extended recording time with wireless pH monitoring in evaluating gastroesophageal reflux disease. Clin Gastroenterol Hepatol. Apr 2005;3(4):329-334. PMID 15822037*
11. *Bajbouj M, Becker V, Neuber M, et al. Combined pH-metry/impedance monitoring increases the diagnostic yield in patients with atypical gastroesophageal reflux symptoms. Digestion. Jan 2007;76(3-4):223-228. PMID 18174685*
12. *Bredenoord AJ, Weusten BL, Timmer R, et al. Addition of esophageal impedance monitoring to pH monitoring increases the yield of symptom association analysis in patients off PPI therapy. Am J Gastroenterol. Mar 2006;101(3):453-459. PMID 16464226*
13. *Mainie I, Tutuian R, Shay S, et al. Acid and non-acid reflux in patients with persistent symptoms despite acid suppressive therapy: a multicentre study using combined ambulatory impedance-pH monitoring. Gut. Oct 2006;55(10):1398-1402. PMID 16556669*
14. *Vela MF, Camacho-Lobato L, Srinivasan R, et al. Simultaneous intraesophageal impedance and pH measurement of acid and nonacid gastroesophageal reflux: effect of omeprazole. Gastroenterology. Jun 2001;120(7):1599-1606. PMID 11375942*
15. *Hirano I, Richter JE. ACG practice guidelines: esophageal reflux testing. Am J Gastroenterol. Mar 2007;102(3):668-685. PMID 17335450*

16. *Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. Mar 2013;108(3):308-328; quiz 329. PMID 23419381*
17. *Kahrilas PJ, Shaheen NJ, Vaezi MF, et al. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology. Oct 2008;135(4):1383-1391, 1391 e1381-1385. PMID 18789939*
18. *National Institute for Health and Care Excellence (NICE). Catheterless oesophageal pH monitoring [IPG187]. 2006; https://www.nice.org.uk/Guidance/IPG187. Accessed December 11, 2018.*
19. *National Institute for Health and Care Excellence (NICE). Gastro-oesophageal reflux disease in children and young people: diagnosis and management [NG1]. 2015; https://www.nice.org.uk/guidance/ng1. Accessed December 11, 2018.*
20. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.20, Esophageal pH Monitoring. November 2018.*

Other:

Mosby's Medical, Nursing, & Allied Health Dictionary 6th edition

X. POLICY HISTORY

TOP

MP 2.017	**CAC 2/24/04**
	CAC 10/26/04
	CAC 10/25/05
	CAC 6/27/06
	CAC 7/31/07
	CAC 3/25/08
	CAC 3/31/09
	CAC 3/30/2010 Consensus
	CAC 7/27/2010 Revised medical necessity language for wireless esophageal pH monitoring. Also revised clinical indication language for catheter-based and wireless esophageal pH monitoring.
	CAC 10/25/11 Adopting BCBSA, Title changed. Deleted information regarding devices (e.g. Bilitec™ 2000) used to monitor bile exposure in the stomach or esophagus. This device is no longer in use. Medically necessary statements 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.

POLICY TITLE	ESOPHAGEAL pH MONITORING
POLICY NUMBER	MP-2.017

	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.
	12/19/17 Consensus review. Policy statements unchanged. Cross-Reference, Description/Background, Rationale and Reference sections updated.
	4/24/18 Admin Update: Admin update to labeling of Impedance Monitoring. Rationale condensed to Summary of Evidence only. Reference to BCBSA added.
	12/11/18 Consensus review. Policy statements unchanged. FEP variation removed as FEP policy was archived 4/15/18. Description/Background, Rationale and Reference sections updated.

Top