MEDICAL POLICY

POLICY TITLE	ESOPHAGEAL PH MONITORING
POLICY NUMBER	MP 2.017

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**7/1/2025**

I. POLICY

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

- Documentation of abnormal acid exposure in endoscopy-negative individuals being considered for surgical anti-reflux repair;
- Evaluation of individuals after anti-reflux surgery who are suspected of having ongoing abnormal reflux;
- Evaluation of individuals with either normal or equivocal endoscopic findings and reflux symptoms refractory to proton pump inhibitor therapy;
- Evaluation of refractory reflux in individuals 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 individuals that have failed to respond to at least 4 weeks of proton pump inhibitor therapy;
- Evaluation of concomitant gastroesophageal reflux disease in individuals with adult-onset, nonallergic asthma suspected of having reflux-induced asthma.

Twenty-four-hour catheter-based esophageal pH monitoring or multichannel intraluminal impedance 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:

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

POLICY TITLE	ESOPHAGEAL PH MONITORING
POLICY NUMBER	MP 2.017

Twenty-four-hour catheter-based impedance pH monitoring may be considered **investigational** in individuals with established gastroesophageal reflux disease (GERD) on proton pump inhibitor (PPI) therapy, whose symptoms have not responded adequately to twice-daily PPI therapy, in order to define refractory GERD. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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

POLICY GUIDELINES

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

Cross-References:

MP 2.053 Procedures for the Treatment for Gastroesophageal Reflux Disease
MP 5.033 Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders
MP 5.047 Ingestible pH and Pressure Capsule

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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.

Several wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared for marketing by the FDA through the 510(k) process. Examples include the Bravo™ pH Monitoring System (Medtronic), the Sandhill Scientific PediaTec™ pH Probe (Sandhill Scientific), the ORION II Ambulatory pH Recorder (MMS, Medical Measurement Systems), and the TRIP CIC Catheter (Tonometrics). FDA product code: FFT. The ZepHr® Reflux Monitoring System (Diversatek) is an impedance device to detect reflux. FDA product code: FFX.

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 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.

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

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health

benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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.

Covered when medically necessary:

Procedure Codes								
91034	91035							

Investigational; therefore, not covered:

Procedure codes								
91037	91038							

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

POLICY TITLE	ESOPHAGEAL PH MONITORING
POLICY NUMBER	MP 2.017

ICD-10-CM Diagnosis Codes	Description
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
K21.00	Gastro-esophageal reflux disease with esophagitis, without bleeding
K21.01	Gastro-esophageal reflux disease with esophagitis, with bleeding
K21.9	Gastro-esophageal reflux disease without esophagitis
P24.80	Other neonatal aspiration without respiratory symptoms
P24.81	Other neonatal aspiration with respiratory symptoms
P28.40	Unspecified apnea of newborn
P284.9	Other apnea of newborn
P28.89	Other specified respiratory conditions of newborn
R00.1	Bradycardia, unspecified
R05	Cough
R05.1	Acute cough
R05.2	Subacute cough
R05.3	Chronic cough
R05.4	Cough syncope
R05.8	Other specified cough
R05.9	Cough, unspecified
R06.1	Stridor
R06.2	Wheezing
R06.81	Apnea, not elsewhere classified
R07.89	Other chest pain

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 2.017	**09/01/2020 Administrative Update.** ICD 10 codes K 21.00 and K21.01 added.

POLICY TITLE	ESOPHAGEAL PH MONITORING
POLICY NUMBER	MP 2.017

	09/11/2020 Consensus Review. Policy Statement unchanged. Coding reviewed, no changes. Product Variation Statement updated. References reviewed, updated.
	03/04/2021 Consensus Review. Updated Summary of Evidence and references. No changes to coding.
	09/07/2021 Administrative Update. Addition of new ICD-10 codes. Effective 10/01/2021.
	09/16/2022 Administrative Update. Deleted ICD10 code P28.4 and added new ICD10 codes P28.40 and P28.49. Effective 10/01/2022
	12/12/2022 Minor Review. Impedance pH monitoring changed from not medically necessary to medically necessary with criteria. Product variation and FEP language revised. Background and Rationale updated. References added.
	12/06/2023 Consensus Review. No change to policy statement. Cross Referenced policies, Rationale, Definitions and References updated.
	12/17/2024 Minor Review. Impedance pH monitoring changed from medically necessary to investigational. Rationale and References updated.

TOP