Corporate Medical Policy

Esophageal pH Monitoring

File Name: esophageal_ph_monitoring
Origination: 4/2011
Last Review: 5/2023

Description of Procedure or Service

Acid reflux is the cause of heartburn and acid regurgitation peptic 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 usually diagnosed by clinical evaluation and treated empirically with medical management For patients who do not respond appropriately to medications, or who have recurrent chronic symptoms, endoscopy is indicated to confirm the diagnosis and assess the severity of reflux esophagitis. In some patients, endoscopy is nondiagnostic, or results are discordant with the clinical evaluation. In these cases, further diagnostic testing may be of benefit.

Esophageal monitoring is done through the use of a tube with a pH electrode attached to its tip, which is then passed to approximately 5 cm above the upper margin of the lower esophageal sphincter (LES). 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, indicating gastric acid reflux over a 24-hour period. Wireless pH monitoring is achieved using endoscopic or manometric guidance to attach the pH measuring capsule on 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 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 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).

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Esophageal pH Monitoring

BCBSNC will provide coverage for esophageal pH monitoring when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When esophageal pH monitoring is covered

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 individuals being considered for surgical antireflux repair,
- Evaluation of individuals after antireflux surgery who are suspected of having ongoing abnormal reflux,
- Evaluation of individuals with either normal or equivocal endoscopic findings and reflux symptoms that are 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 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.

24-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:

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

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

When esophageal pH monitoring is not covered

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

Policy Guidelines

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. 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, and use in some of these

subpopulations is also supported in clinical practice guidelines. As a result, esophageal pH monitoring may be considered medically necessary for selected subpopulations when criteria are met.

The American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD in 2008. 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 proton pump inhibitor 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *91034, 91035, 91037, 91038*

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

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Kahrilas PJ, Shaheen NJ, Vaezi MF et al. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology 2008; 135(4):1383-1391.

Kahrilas PJ, Shaheen NJ, Vaezi MF. American Gastroenterological Association Institute technical review on the management of gastroesophageal reflux disease. Gastroenterology 2008; 135(4):1392-1413.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 3/11/2010

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Wireless Esophageal pH Monitoring. TEC Assessments 2006; Volume 21, Tab 2

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 4/14/2011

Medical Director review – 10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 10/4/2011

Specialty Matched Consultant Advisory Panel 4/18/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 7/12/12

Specialty Matched Consultant Advisory Panel 4/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 6/13/13

Specialty Matched Consultant Advisory Panel 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 6/12/14

Specialty Matched Consultant Advisory Panel 5/2015

Medical Director review 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 6/11/15

Specialty Matched Consultant Advisory Panel 5/2016

Medical Director review 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 11/2016

Medical Director review 11/2016

Specialty Matched Consultant Advisory Panel 5/2017

Medical Director review 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 11/2017

Specialty Matched Consultant Advisory Panel 5/2018

Medical Director review 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 11/2018

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 12/2019

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 5/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 12/2020

Specialty Matched Consultant Advisory Panel 5/2021

Medical Director review 5/2021

Specialty Matched Consultant Advisory Panel 5/2022

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel 5/2023

Medical Director review 5/2023

Policy Implementation/Update Information

5/10/11 New policy developed. BCBSNC will provide coverage for esophageal pH monitoring when it is determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)

11/8/11 Description section updated to include information regarding impedance-pH monitoring. The following statement was added to the Not Covered section: "24-hour catheter-based impedance-pH monitoring is considered not medically necessary." Billing/Coding section and Policy Guidelines updated. (adn)

5/1/12 CPT code 91037 removed from policy as it is not a monitoring code. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)

9/18/12 Reference added. Added wireless pH monitoring to the first medically necessary policy statement; third policy statement on 48- to 96-hour, catheter-free, wireless esophageal monitoring deleted. First policy statement under When Not Covered section deleted. Added monitoring must be done in accordance with FDA approved indications and age ranges to policy statement. Policy Guidelines updated. Medical Director review 9/1/12. (sk)

4/30/13 Specialty Matched Consultant Advisory Panel review 4/17/13. No change to policy statement. (sk)

5/13/14 Removed "24-hour" from the policy statement on impedance monitoring as catheter-based impedance monitoring for any length of time is considered not medically necessary. No other changes to policy statements. Specialty Matched Consultant Advisory Panel review 4/29/14. Policy noticed 5/13/14 for effective date 7/15/14. (sk)

8/26/14 Reference added. No change to Policy statement. (sk)

7/1/15 References updated. Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements remain unchanged. (td)

7/28/15 References updated. (td)

7/1/16 Description section slightly revised, adding "alarm symptoms such as Dysphagia or iron deficiency anemia or" per Consultant recommendation. Updated Policy Guidelines. Specialty Matched Consultant Advisory Panel review 5/25/2016. (jd)

12/30/16 Minor update to Policy Guidelines and references updated. Medical Director review 11/2016. (jd)

6/30/17 Specialty Matched Consultant Advisory Panel 5/2017. Medical Director review 5/2017. (jd)

6/8/18 References updated. Specialty Matched Consultant Advisory Panel 5/2018. Medical Director review 5/2018. (jd)

5/28/19 Minor revision to Description section. Regulatory Status section added and references updated. Specialty Matched Consultant Advisory Panel 5/2019. Medical Director review 5/2019. (jd)

6/9/20 References updated. Specialty Matched Consultant Advisory Panel 5/2020. Medical Director review 5/2020. (jd)

6/1/21 References updated. Specialty Matched Consultant Advisory Panel 5/2021. Medical Director review 5/2021. (jd)

6/30/22 Policy title updated. Policy formatting updated to align with the new utilization management tool. No changes to policy statement or intent.Minor update to Description section. Specialty Matched Consultant Advisory Panel 5/2022. Medical Director review 5/2022. (jd)

5/30/23 Description, Policy Guidelines and References sections updated. When Covered section edited for clarity, no change to policy statement. Specialty Matched Consultant Advisory Panel 5/2023. Medical Director review 5/2023. (tm)