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OVERVIEW

Esophageal pH monitoring using wired or wireless devices can record the pH of the lower esophagus for a period of 1 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.

Note: This policy addresses the following procedures: Esophageal pH Monitoring (wireless or catheter-based) and Catheter-based Impedance-pH Monitoring.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Esophageal pH monitoring using a wireless or catheter-based system may be considered medically necessary in adults and children or adolescents able to report symptoms.

The use of 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.

The use of 24-hour catheter-based impedance pH monitoring 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 is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

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 (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 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 is able to 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). The ZepHr® Reflux Monitoring System (Diversatek) is an impedance device to detect reflux.

For individuals who have gastroesophageal reflux disease (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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are considered medically necessary for Medicare Advantage Plans and Commercial Products when filed with one of the covered ICD-10 Diagnosis Codes* listed below:

- 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

The above CPT code(s) are considered medically necessary when filed with one of the ICD-10 CM Diagnosis Codes* included in the attached list below:

[*Covered Diagnosis Codes for Esophageal pH Monitoring \(CPTs 91034/91035\)](#)

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, May 2026
Provider Update, January 2026
Provider Update, January 2025
Provider Update, January 2024
Provider Update, March 2022

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