Medical Coverage Policy | Esophageal pH Monitoring

EFFECTIVE DATE:10|15|2015
POLICY LAST UPDATED: 12|17|2019

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.

MEDICAL CRITERIA
Not applicable.

PRIOR AUTHORIZATION
Prior authorization review is not required.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial
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.

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.

Catheter-based impedance-pH monitoring may increase positive tests or diagnostic yield, the potentially increased sensitivity may be accompanied by a decrease in specificity and the net effect on patient management and patient outcomes is not certain. 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.

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
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.

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.

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.

For individuals who have 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 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 indirect chain of evidence supporting the utility of the test is weak. T he 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 in different populations evaluating test performance and diagnostic yield. Relevant outcomes include test accuracy and validity, symptoms, and functional outcomes. Positive wireless 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. Some studies have shown higher positive test rates with prolonged wireless monitoring 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 individuals who have 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 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 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, 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.
Expert clinical opinion 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

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) 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."
A number of 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.

CODING

The following CPT codes are medically necessary when filed with a covered diagnosis:
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

Covered ICD 10 Diagnosis
G47.30-G47.33
J37.0
J45.20-J45.99
J69.0
K21.0-K21.9
P28.0-P28.9
R00.1
R05
R06.81
R06.1
R06.2

The following CPT codes are not medically necessary:
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

None

PUBLISHED

Provider Update, February 2020
Provider Update, November/December 2018
Provider Update, January 2018
Provider Update, January 2017
Provider Update, August 2015

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