01-91000-01

Original Effective Date: 08/15/01

Reviewed:12/7/23

Revised: 12/15/23

Subject: Esophageal pH Monitoring

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Acid reflux is the cause of heartburn, acid regurgitation esophagitis, and Barrett's esophagus and can be a cause of esophageal stricture, posterior laryngitis, some cases of asthma, chronic cough, chronic hoarseness, dental erosions, pharyngitis subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia. Gastroesophageal reflux disease (GERD) is usually diagnosed by clinical history and endoscopy, and is treated empirically with a trial of medical management.

Esophageal pH monitoring is a technique used for diagnosing gastroesophageal reflux disease and the duration of time required for the esophagus to clear the acid. A tube containing a pH (anti-log of hydrogen ion concentration) electrode is passed through the nose and positioned in the esophagus 5 cm above the upper margin of the lower esophageal sphincter (LES). For 24-hour monitoring, the electrode is then connected to a pH meter/recorder that is worn by the patient on a waist belt or shoulder strap. The patient keeps a record of each time reflux symptoms occur. The recorder provides a continuous record (chart) of the pH of the esophagus, which can later be analyzed and correlated with the symptoms recorded by the patient. Esophageal pH monitoring is performed either during esophageal manometry or as a prolonged study in ambulatory patients (24-hour pH monitoring).

A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System, Medtronic) has been cleared for marketing by the U.S. Food and Drug Administration (FDA) for the purposes of esophageal monitoring. Using endoscopic or manometric guidance, the capsule is temporarily implanted in the esophageal mucosa using a pin. The capsule records pH levels for up to 48 hours and transmits them via radio frequency telemetry to a receiver worn in the patient's belt. Data from the recorder are uploaded to a computer for analysis by a nurse or doctor.

Several wireless and catheter-based (wired) esophageal pH monitoring devices have been cleared for marketing by FDA through the 510(k) process (e.g., Bravo pH Monitoring System (Given Imaging), the Sandhill Scientific PediaTec™ pH Probe (Sandhill Scientific), TRIP CIC Catheter (Tonometrics)).

POSITION STATEMENT:

Esophageal pH monitoring using a catheter-based system **OR** wireless system **meets the definition of medical necessity** for **ANY** of the following clinical indications in adults and children who are able to report symptoms:

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

Esophageal pH monitoring (twenty-four hour catheter based) **meets the definition of medical necessity** for 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
- Recurrent pneumonia.

Catheter based impedance pH monitoring for GERD is considered **experimental or investigational** in members 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

BILLING/CODING INFORMATION:

The following codes may be used to describe esophageal pH monitoring:

CPT Coding

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

ICD-10 Diagnosis Codes That Support Medical Necessity for 90134 and 90135

G47.30 – G47.33	Sleep apnea, unspecified
I49.8	Other specified cardiac arrhythmias
J02.8	Acute pharyngitis due to other specified organisms
J02.9	Acute pharyngitis, unspecified
J04.0	Acute laryngitis
J31.2	Chronic pharyngitis
J37.0	Chronic laryngitis
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma, uncomplicated
J45.30	Mild intermittent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent, uncomplicated asthma NOS
J45.41	Moderate persistent with (acute) exacerbation
J45.42	Moderate persistent with status asthmaticus
J45.50	Severe persistent, uncomplicated asthma NOS
J45.51	Severe persistent with (acute) exacerbation
J45.52	Severe persistent with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.990	Exercise induced bronchospasm
J45.991	Cough variant asthma
J45.998	Other asthma
J69.0	Pneumonitis due to inhalation of food and vomit
K21.00 – K21.9	Gastro-esophageal reflux disease without esophagitis
P22.8	Other respiratory distress of newborn
P22.9	Respiratory distress of newborn, unspecified
P24.30	Neonatal aspiration of milk and regurgitated food without respiratory symptoms
P24.31	Neonatal aspiration of milk and regurgitated food with respiratory symptoms
P28.0 – P28.9	Other respiratory conditions originating in the perinatal period

P29.12	Neonatal bradycardia
P84	Other problems with newborn
R00.1	Bradycardia, unspecified
R05.1 – R05.9	Cough
R06.00	Dyspnea NOS
R06.09	Other forms of dyspnea
R06.1	Stridor
R06.2	Wheezing
R06.5	Mouth breathing
R06.7	Sneezing
R06.81	Apnea, not elsewhere classified
R06.89	Other abnormalities of breathing
R19.6	Halitosis

REIMBURSEMENT INFORMATION:

Esophageal manometry, when used for pH tip placement, is considered incidental to the pH recording. There is no specific procedure code for reporting esophageal manometry.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

The following National Coverage Determinations (NCDs) was reviewed on the last guideline reviewed date: 24-Hour Ambulatory Esophageal pH Monitoring, (100.3) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Anti-reflux surgery: surgical procedure of the esophagus and stomach in an attempt to stop or decrease secretions from backing up into the esophagus.

Barrett's esophagus: metaplasia of the lower esophagus that is characterized by replacement of squamous epithelium with columnar epithelium, occurs especially as a result of chronic gastroesophageal reflux, and is associated with an increased risk for esophageal carcinoma – called also Barrett's epithelium.

Esophageal manometry: determines the pressure in the upper and lower esophageal sphincters and the effectiveness and coordination of propulsive movements and detects abnormal contractions. It is

used to diagnose achalasia, diffuse spasm, scleroderma, and lower esophageal sphincter hypo – and hypertension and to evaluate esophageal function for certain therapeutic procedures (e.g., anti-reflux surgery, pneumatic dilation for achalasia). It is performed by passing a small tube past the throat and into the esophagus. Complications are extremely uncommon but may include trauma to the nasal passages.

Stridor: wheezing heard in the neck area upon inhalation and exhalation.

RELATED GUIDELINES:

Ingestible pH and Pressure Capsule, 01-91000-08
Wireless Capsule Endoscopy, 01-91000-05

OTHER:

Other names used to report esophageal pH monitoring:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Acid reflux test
Catheter based impedance pH monitoring
Esophageal pH monitoring
Esophageal pH recording
Esophagus acid reflux test
Gastroesophageal reflux testing
ORION II Ambulatory pH Recorder (Medical Measurement Systems (MMS))

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/7/23.

GUIDELINE UPDATE INFORMATION:

08/15/01	Medical Coverage Guideline Revised and Reformatted.
10/15/03	Reviewed; added information regarding 48-hour catheter-free capsule pH monitoring systems (investigational)
01/01/05	Annual HCPCS coding update; consisting of deletion of CPT codes 91032 and 91033 and addition of CPT codes 91034, 91035, 91037 and 91038.
10/15/05	Scheduled review and revision of guideline; consisting of updated references.
08/15/06	Review and revision of guideline consisting of updated references.
07/15/07	Annual review; current coverage and limitations maintained, reformatted guideline, references updated.
07/15/08	Review and revision of guideline consisting of updated references.
06/15/10	Annual review. Updated ICD-9 diagnosis codes; revised descriptor (427.89, 476.0, 780.57, 784.9, 786.09, and 786.2), added 4th digit (493.00 – 493.92), and added diagnosis codes: 779.81, 786.03, and 786.07. Deleted related Internet links. Updated references.
01/15/11	Revision; related ICD-10 codes added.
05/11/14	Revision: Program Exceptions section updated.
10/01/15	Revision; updated ICD9 and ICD10 coding section.
11/01/15	Revision: ICD-9 Codes deleted.
04/15/17	Added catheter based impedance pH monitoring for GERD and deleted esophageal pH recording to detect or verify reflux esophagitis.
12/15/19	Review; no change in position statement. Updated references.
12/15/21	Review; no change in position statement (format change). Updated references.
10/01/22	Annual CPT/HCPCS update. Added code range G47.30-G47.33, K21.00-K21.9, P28.0-P28.9 and R05.1-R05.9.
05/22/23	Update to Program Exceptions section.
12/15/23	Review; revise position statement. Updated references.