Anthem

Clinical UM Guideline

Subject: Esophageal pH Monitoring
Guideline #: CG-MED-02
Status: Revised

Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description

This document addresses the use of standard catheter-based 24 hour and wireless-based 48 hour esophageal pH monitoring for all indications.

Clinical Indications

Medically Necessary:

Esophageal pH monitoring is considered **medically necessary** for the following adults, children or adolescents who are able to report their symptoms in the following clinical situations:

A. Documentation of abnormal esophageal acid exposure in endoscopy-negative individuals being considered for surgical antireflux repairs (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
B. Evaluation of antireflux surgery in individuals who are suspected to have ongoing abnormal reflux (pH study done after withholding antisecretory drug regimen for at least 1 week); **or**
C. Evaluation of individuals with either normal or equivocal endoscopic finding and reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy (pH study after withholding antisecretory drug regimen for at least 1 week if the study is done to confirm excessive acid exposure or while taking the antisecretory drug regimen if the symptom-reflux correlation is to be scored); **or**
D. To detect refractory reflux in individuals with chest pain after cardiac evaluation using a symptom reflux association scheme, preferably the symptoms association probability calculation (pH study done after a trial of PPI therapy for at least 4 weeks); **or**
E. To evaluate an individual with suspected otolaryngologic manifestations (laryngitis, pharyngitis, chronic cough) of gastroesophageal reflux disease after symptoms have failed to respond to at least 4 weeks of PPI therapy (pH study done while the individual continues taking their antisecretory drug regimen to document the adequacy of therapy); **or**
F. To document concomitant gastroesophageal reflux disease in an adult onset, non-allergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding antisecretory drugs for at least 1 week).

Esophageal pH monitoring is considered **medically necessary** in infants or children who are unable to report or describe symptoms of reflux with:

A. Unexplained apnea; **or**
B. Bradycardia; **or**
C. Refractory coughing, wheezing, stridor or recurrent choking (aspiration);**or**
D. Persistent or recurrent laryngitis; **or**
E. Recurrent pneumonia.

Not Medically Necessary:

Esophageal pH monitoring is considered **not medically necessary** when the criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
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
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)

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Gastroesophageal reflux disease (GERD) is a disease where the lower esophageal sphincter that separates the esophagus from the stomach becomes weakened and allows acidic stomach contents to flow backwards into the esophagus. GERD is associated with heartburn, Barrett's esophagus, esophageal stricture, some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis, subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia. GERD is usually

diagnosed by clinical history and is typically treated initially with an empiric trial of PPI. Individuals who do not respond to PPI therapy or present with more complex symptoms are often referred to endoscopy with pH monitoring for further evaluation. The pH monitoring provides quantitative data on both esophageal acid exposure and on the temporal correlation between individual symptoms and reflux events.

Conventional catheter-based pH monitoring involves the placement of a catheter with a pH electrode attached to its tip within the esophagus at 5 cm above the upper margin of the lower esophageal sphincter (LES). The electrode is attached to an electronic 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. Subjective symptoms are also manually reported in a patient log; these symptoms can then be temporally related to acid reflux events.

Non catheter-based (i.e. wireless) devices have become available. One such device is the Bravo™ capsule, which is attached to the esophageal wall during an endoscopy procedure. The Bravo capsule contains a sensor that transmits pH data via radio waves to a small data collection device worn on the belt. The Bravo capsule is naturally dislodged from the esophagus in a short period of time. The sensor is then passed through the digestive tract.

In 2022 the American College of Gastroenterology (ACG) published their clinical guideline for the diagnosis and management of gastroesophageal reflux disease (Katz, 2022). In that document, they make the following suggestions:

> We suggest esophageal pH monitoring (Bravo, catheter-based, or combined impedance-pH monitoring) performed OFF PPIs if the diagnosis of GERD has not been established by a prior pH monitoring study or an endoscopy showing long-segment Barrett's esophagus or severe reflux esophagitis (Los Angeles grade C or D). (Conditional recommendation, low level of evidence)
>
> We suggest esophageal impedance pH monitoring performed ON PPIs for patients with an established diagnosis of GERD whose symptoms have not responded adequately to twice-daily PPI therapy. (Conditional recommendation, low level of evidence)
>
> An issue that frequently arises is whether esophageal pH monitoring should be performed on or off PPI therapy. It is generally recommended to monitor after PPIs are stopped for 7 days if the diagnosis of GERD is not clear, and prior to antireflux surgery or endoscopic therapy for GERD to document abnormal acid reflux [16]. This recommendation includes testing with either the telemetry capsule (48-96 hours) or impedance-pH catheter. Reflux monitoring while on PPI therapy is suggested in patients who have had the diagnosis of GERD established by previous objective evidence (i.e. erosive esophagitis, Barrett's esophagus, prior pH testing off PPI) but who have symptoms potentially reflux-related that have not responded to PPIs. In these patients, impedance/pH testing is recommended to document reflux hypersensitivity for weakly acidic or non-acidic reflux as well as for acid reflux.

These suggestions are made on the basis of a low level of evidence.

Definitions

Endoscopy: An examination of the interior of a canal or hollow viscus by means of a special instrument, such as an endoscope.

Esophageal pH monitoring: A medical test that measures the acidity in the esophagus.

References

Peer Reviewed Publications:

1. Ang D, Teo EK, Ang TL, et al. To Bravo or not? A comparison of wireless esophageal pH monitoring and conventional pH catheter to evaluate non-erosive gastroesophageal reflux disease in a multiracial Asian cohort. J Dig Dis. 2010; 11(1):19-27.
2. Belafsky PC, Allen K, Castro-Del Rosario L, Roseman D. Wireless pH testing as an adjunct to unsedated transnasal esophagoscopy: the safety and efficacy of transnasal telemetry capsule placement. Otolaryngol Head Neck Surg. 2004; 131(1):26-28.
3. DeVault KR, Castell DO. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. Am J Gastroenterol. 2005; 100(1):190-200.
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5. Pandolfino JE, Bianchi LK, Lee TJ, et al. Esophagogastric junction morphology predicts susceptibility to exercise-induced reflux. Am J Gastroenterol. 2004; 99(8):1430-1436.
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7. Pandolfino JE, Schreiner MA, Lee TJ, et al. Comparison of the Bravo wireless and Digitrapper catheter-based pH monitoring systems for measuring esophageal acid exposure. Am J Gastroenterol. 2005; 100(7):1466-1476.
8. Prakash C, Clouse RE. Value of extended recording time with wireless pH monitoring in evaluating gastroesophageal reflux disease. Clin Gastroenterol Hepatol. 2005; 3(4):329-334.
9. Tu CH, Lee YC, Wang HP, et al. Ambulatory esophageal pH monitoring by using a wireless system: a pilot study in Taiwan. Hepatogastroenterology. 2004; 51(60):1586-1589.
10. Ward EM, Devault KR, Bouras EP, et al. Successful oesophageal pH monitoring with a catheter-free system. Aliment Pharmacol Ther. 2004; 19(4):449-454.
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12. Wong WM, Bautista J, Dekel R, et al. Feasibility and tolerability of transnasal/per-oral placement of the wireless pH capsule vs traditional 24-hr esophageal pH monitoring- a randomized trial. Aliment Pharmacol Ther. 2005 15; 21(2):155-163.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Gastroenterological Association Medical Position Statement: Guidelines on the use of esophageal pH recording. Gastroenterology. 1996; 110(6):1981.
2. Centers for Medicare and Medicaid Services. National Coverage Determination for 24-Hour Ambulatory Esophageal pH Monitoring. NCD #100.3. Effective June 11, 1985. Available at: https://www.cms.gov/. Accessed on August 7, 2023.
3. Chotiprashidi P, Liu J, Carpenter S, et al. ASGE Technology Status Evaluation Report: wireless esophageal pH monitoring system. Gastrointest Endosc. 2005; 62(4):485-487.
4. Gyawali CP, Carlson DA, Chen JW, et al. ACG clinical guidelines: Clinical use of esophageal physiologic testing. Am J Gastroenterol. 2020; 115(9):1412-1428.

5. Hirano I, Richter JE; Practice Parameters Committee of the American College of Gastroenterology. ACG practice guidelines: esophageal reflux testing. Am J Gastroenterol. 2007; 102(3):668-685.
6. Kahrilas PJ, Shaheen NJ, Vaezi MF, American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology. 2008; 135(4):1383-1391.
7. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2022; 117(1):27-56.

Websites for Additional Information

1. National Library of Medicine. Medical encyclopedia: Gastroesophageal reflux disease. Last update: June 9, 2021. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/000265.htm. Accessed on August 7, 2023.

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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.

History

Status	Date	Action
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting in Clinical Indications section. Added “when the criteria above have not been met” to NMN statement. Revised References sections.
Reviewed	08/11/2022	MPTAC review. Updated review date, References, Websites for Additional Information and History sections.
Reviewed	08/12/2021	MPTAC review. Updated review date, References, Websites for Additional Information and History sections.
Reviewed	08/13/2020	MPTAC review. Updated review date, References, Websites for Additional Information and History sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated review date, References, Websites for Additional Information and History sections.
Reviewed	09/13/2018	MPTAC review. Updated review date, References, Websites for Additional Information and History sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Minor format changes to the Clinical Indications section. Updated review date, References and History sections.
Reviewed	11/03/2016	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated review date, References and History sections. Updated formatting in the Position Statement section.
Reviewed	11/05/2015	MPTAC review. Updated review date, References and History sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated review date, References and History sections.
Revised	11/14/2013	MPTAC review. In the not medically necessary criteria, added language to indicate esophageal pH monitoring is not medically necessary to establish a diagnosis of GERD in individuals with Barrett’s esophagus. Updated review date, References and History sections.
Reviewed	11/08/2012	MPTAC review. Updated review date, References and History sections.
Reviewed	11/17/2011	MPTAC review. Updated review date, Coding, References and History sections.
Reviewed	11/18/2010	MPTAC review. Updated review date, References and History sections.
Reviewed	11/19/2009	MPTAC review. Typographical error corrected in third bullet of the medical necessity criteria. No change to the intent of the document. Updated review date, Description, References and History sections. Removed Place of Service/Duration section.
Reviewed	11/20/2008	MPTAC review. Updated review date, references and history sections.
Revised	11/29/2007	MPTAC review. As a result of MED.00045 (Wireless Esophageal pH Monitoring) being archived, CG-MED-02 revised to address both catheter-based and wireless esophageal pH monitoring. Updated review date, Discussion/General Information, Coding, References and History sections. Title changed to “Esophageal pH Monitoring” in order to address both wireless and catheter-based esophageal pH monitoring.
	10/01/2007	Updated coding section with 10/01/2007 ICD-9 changes.
Reviewed	05/17/2007	MPTAC review. No change to guideline position statement. Updated Coding section; removed CPT 91033 deleted 12/31/2004.
Reviewed	06/08/2006	MPTAC review. No change to position statement. Added reference to MED.00045 Wireless Esophageal pH Monitoring. Updated Reference and Coding sections.
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			No document
WellPoint Health Networks, Inc.	09/23/2004	2.06.01	Esophageal pH Monitoring

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.