Prior Authorization Review Panel
MCO Policy Submission

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Plan: AmeriHealth Caritas Pennsylvania Community Health Choices	**Submission Date**: 8/26/2022
Policy Number: CCP.1391	**Effective Date:** 8/2018 **Revision Date:** August 2, 2022
Policy Name: Esophageal pH monitoring	
Type of Submission – Check all that apply: ☑**New Policy** **XRevised Policy*** ☐ **Annual Review – No Revisions** ☐ **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Please see the tracked changes for the updates.	
Name of Authorized Individual (Please type or print): Akintayo Akinlawon, MD	**Signature of Authorized Individual:** 

Esophageal pH monitoring

Clinical Policy ID: CCP.1391

Recent review date: 8/2022

Next review date: 12/2023

Policy contains: Gastroesophageal reflux disease; esophageal pH monitoring; impedance-pH monitoring; reflux testing.

AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Ambulatory 24-hour esophageal catheter-based pH, wireless pH, or combined impedance-pH monitoring is clinically proven and, therefore, medically necessary for the following indications (Goncalves, 2020; Kahrilas, 2008; Katz, 2013; Rosen, 2018):

- Pre-surgical evaluation of members with non-erosive esophagitis (withholding anti-secretory medication for seven days).
- Suspected abnormal reflux after anti-reflux surgery (withholding anti-secretory medication for seven days).
- Persistent extra-esophageal symptoms (e.g., asthma, chronic cough, and laryngitis) after a negative or inconclusive evaluation on specialty referral and suspicion of gastroesophageal reflux disease prior to a trial of proton pump inhibitor therapy.
- Refractory reflux after a four-week trial of proton pump inhibitor therapy to confirm excessive acid exposure (withholding anti-secretory regimen for at least seven days) or to correlate symptom and reflux (on anti-secretory drug regimen) in members with:
    - Typical symptoms of gastroesophageal reflux disease and normal or equivocal esophagogastroduodenoscopy findings.
    - Persistent extra-esophageal symptoms and a negative or inconclusive evaluation on specialty referral.
    - Persistent chest pain after cardiac causes have been ruled out.

- For children ages 18 years or younger with frequent regurgitation and/or episodic vomiting to diagnose possible gastroesophageal reflux disease and to rule out other diagnoses.

Limitations

Wireless pH esophageal monitoring using the Bravo® pH Monitoring System (Medtronic, Minneapolis, Minnesota) is not medically necessary in members younger than age 4 years, because it has not been approved for use in this age group (U.S. Food and Drug Administration, 2010).

All other uses of ambulatory esophageal pH monitoring are not medically necessary, including, but not limited to, members with (Katz, 2013; Katz 2022; Rosen, 2018):

- Classic symptoms of gastroesophageal reflux disease effectively treated with acid suppression therapy.
- Endoscopy-positive gastroesophageal reflux disease.
- Short or long-segment Barrett's esophagus to establish a diagnosis of gastroesophageal reflux disease.

Alternative covered services

- Empirical acid suppression medications.
- Gastroenterology consultation.
- Esophagogastroduodenoscopy.
- Manometry.
- Barium contrast study.
- Scintigraphy.
- Fundoplication surgery.
- Bariatric surgery in obese patients.

Background

Gastroesophageal reflux is a normal physiologic process that occurs several times a day in healthy persons of all ages. Pathology occurs when there is a poorly functioning esophagogastric junction resulting in loss of the protective upper digestive tract mechanisms, extending to insufficient clearing and buffering of refluxate, delayed gastric emptying, abnormalities in epithelial restitution and repair, or decreased neural protective reflexes of the aerodigestive tract. Reflux esophagitits develops as a result when the gastric acid triggers the release of cytokines and chemokines that attract inflammatory cells which may contribute to the disease symptoms (Katz, 2022). Simplified; gastroesophageal reflux disease is a condition that develops when the reflux of stomach contents causes troublesome symptoms and complications; it is further subclassified into esophageal and extra-esophageal syndromes (Vandenplas, 2009).

As many as 50% of all patients experiencing gastroesophageal reflux symptoms do not get relief from acid suppressive medication therapy such as antacids, prokinetics, proton pump inhibitors and (H2) histamine blockers (Yadlapati, 2022). Typical symptoms in adults are heartburn and regurgitation and may involve extra-esophageal manifestations such as respiratory and laryngeal symptoms. In infants and young children, common symptoms vary widely and may include regurgitation or vomiting associated with irritability, anorexia or feeding refusal, poor weight gain, dysphagia, presumably painful swallowing, and arching of the back during feedings. Children who have other underlying medical conditions (e.g., prematurity, neurologic impairment, and pulmonary problems) are at greater risk for gastroesophageal reflux disease (Vela, 2014).

Critical to care management is identifying patients who can be managed with conservative treatment in primary care versus those who require consultation with the gastroenterologist. A presumptive diagnosis of gastroesophageal reflux disease can often be established based on presentation of typical symptoms and response to acid suppression with proton pump inhibitors; yet, in infants, acid-suppression therapy may be

ineffective, and no single symptom or cluster of symptoms can reliably predict treatment response (Lightdale, 2013). Diagnostic uncertainty may persist with the presence of alarm symptoms (e.g., evidence of dysphagia, odynophagia, gastrointestinal bleeding, and unintentional weight loss), a refractory response to proton pump inhibitors, and extra-esophageal presentations (Vela, 2014).

Esophagogastroduodenoscopy (EGD or upper endoscopy) may be indicated to assess mucosa and rule out other conditions (e.g., malignancy, stricture, Barrett's esophagus, and eosinophilic esophagitis). However, an increasing number of patients with refractory reflux have normal endoscopic findings (also called non-erosive reflux disease), and abnormal endoscopic findings may not distinguish gastroesophageal reflux disease from other causes (e.g., severe erosive esophagitis and/or long segment Barrett's esophagus) (Gawron, 2013). According to American Gastroenterology Association guidelines, candidacy to undergo invasive anti-reflux procedures would include evidence for pathological gastroesophageal reflux (GERD), exclusion of achalasia and and peristaltic function analysis (Yadlapati, 2022).

Ambulatory esophageal pH monitoring

Ambulatory esophageal pH monitoring, or reflux testing, quantifies the time the esophagus is exposed to acid (measured as the percentage of the day with esophageal pH < 4) and detects reflux events (Vardar, 2017). A study can be performed off acid suppressive medication to measure reflux severity or on acid suppressive medication to assess therapeutic effectiveness.

Reflux testing is available in three forms — catheter-based, wireless, and combined with impedance. Conventional esophageal pH monitoring was first introduced in the 1970s as a 24-hour transnasal, catheter-based system. The limitations of a catheter-based system include patient discomfort, electrode migration, a detectable pH range of less than 4, and a short 24-hour monitoring period that may prevent adequate correlation of symptoms with reflux events and yield erroneous results.

Wireless pH monitoring was developed to circumvent many of the limitations seen with catheter-based monitoring (Gawron, 2010). A radiotelemetry pH sensing capsule is delivered transorally or transnasally during an esophagogastroduodenoscopy or manometry and secured via suction to the esophageal mucosa approximately 6 cm proximal to the squamocolumnar junction. Fixed positioning avoids the discomfort of a nasal catheter; minimizes confounding influences, such as patient movement and hiatus hernia; and allows the recording period to be extended to 48 hours or longer. An example is the Bravo® pH monitoring system (Medtronic, Minneapolis, Minnesota) (U.S. Food and Drug Administration, 2010).

A multi-channel impedance catheter combined with a conventional pH sensor simultaneously detects acid content and direction of movement of the content in the esophageal lumen, either from proximal to distal (swallow) or from distal to proximal (reflux) (Gawron, 2010). Impedance-pH monitoring can detect pH at any value and the height and composition (liquid, gas, or mixed) of the refluxate, and distinguish swallowing from gastroesophageal reflux. Patient tolerability is similar to conventional pH monitoring.

Pathologic acid reflux episodes are defined by an intra-esophageal pH of less than 4 or a decrease in intra-esophageal pH of one unit (over a 24-hour monitoring period). A diagnosis of gastroesophageal reflux disease is established if more than 7% of the measured pH values are less than 4. However, normal pH results may not exclude a diagnosis of gastroesophageal reflux disease (Vardar, 2017).

Findings

We identified three systematic reviews and four evidence-based guidelines to inform this policy. The systematic reviews provide evidence of comparative effectiveness for the three ambulatory reflux testing systems in adult (Iluyomade, 2017; Kessels, 2014) and pediatric populations (van der Pol, 2013).

A systematic review (Kessels, 2014) of 75 studies found that for each monitoring type, the sensitivity ranged from 59% to 100%, and the specificity ranged from 66% to 100%. The diagnostic accuracy of each monitoring type varied widely depending on the enrolled population, cut-off values, reference standards, and study designs used. Adverse events were rare for all monitoring types. The superiority of one monitoring type over another could not be determined based solely on these estimates, as each had its own benefits and limitations.

A systematic review (Iluyomade, 2017) of three randomized controlled trials (n =167 adult patients) found that, compared to catheter-based pH monitoring, wireless pH monitoring was associated with significantly more perceived chest pain, less overall discomfort and negative impact on normal daily activities, and comparable failure rates and recording efficacy. Wireless monitoring detects significantly fewer reflux events, but has a significantly higher diagnostic yield attributable to the longer recording period (48 hours or more). The added value of combined multichannel impedance-pH lies in its ability to detect nonacidic reflux, which would otherwise go undetected by standard pH probe analysis following acid-suppression therapy. Characterizing the composition and direction of refluxate can further inform the diagnosis in persons presenting with atypical symptoms.

A systematic review (van der Pol, 2013) of six studies of 408 total participants (ages 1 month – 13.6 years) and 145 controls (ages 1 month – 16.9 years) assessed the diagnostic accuracy of pH monitoring, two of which included esophagogastroduodenoscopy (macroscopy and histology), compared with history and physical examination. Nearly all studies of esophageal pH monitoring used glass electrode catheters and not the preferred ion sensitive field effect transistor catheters, which provide more accurate in vivo measurements of acid exposure time. The range of reported sensitivity and specificity in three of the studies was broad and unreliable because of poor methodological quality.

Evidence-based guidelines provide recommendations for reflux testing in adult (Kahrilas, 2008; Katz, 2022) and pediatric (National Institute for Health and Care Excellence, 2015; Rosen, 2018) populations. Guidelines agree that ambulatory impedance-pH, catheter pH, or wireless pH esophageal monitoring (off acid suppression therapy) can resolve an uncertain diagnosis of gastroesophageal reflux disease and direct treatment for the following indications:

- Pre-surgical evaluation of patients with non-erosive esophagitis.
- Patients who are refractory after a trial of empirical proton pump inhibitor therapy and either:
    - Negative findings on endoscopy, if presenting with typical symptoms.
    - Negative or inconclusive evaluation by an otorhinolaryngologist, pulmonary, and allergy specialist, if presenting with extra-esophageal symptoms such as asthma, cough, and laryngitis.
- Before a trial of proton pump inhibitors (typically four weeks) in patients with extra-esophageal symptoms and suspicion of gastroesophageal reflux disease.
- To assess the cause of esophageal eosinophilia in selected cases.
- To assess the effectiveness of surgical repair.

There is a lack of consensus on the optimal time to be on empirical proton pump inhibitor therapy prior to reflux testing, but a four-week trial of proton pump inhibitor therapy is generally sufficient to determine treatment response. The choice of reflux test should be based on the patient's clinical presentation and pretest likelihood of gastroesophageal reflux disease, as well as the available technology and expertise. Combined impedance-pH monitoring is often preferred, where available, when nonacid or weakly acid reflux may be relevant or other atypical gastroesophageal reflux disease symptoms are present, particularly in infants and young children.

In 2019, we identified no newly published, relevant literature to add to the policy.

In 2020, we added an updated guideline from the National Institute for Health and Care Excellence (2019) on gastroesophageal reflux disease in children and young people. There were no changes to their recommendations, and no policy changes are warranted.

In 2021 the American College of Gastroenterology guideline endorses the use of pH monitoring in their recommendations as well (Gyawali, 2020). Prolonged wireless pH monitoring can show esophageal acid exposure variations and augment the diagnosis of pathologic gastroesphageal reflux disease even when the first 24 hours of a multiday study is negative for gastroesophageal reflux disease (Gyawali, 2020). In comparison studies “multichannel intraluminal impedance-pH was considered a safe and effective tool, presenting higher sensitivity values than pHmetry regarding the diagnosis of gastroesophageal reflux disease.” (Goncalves, 2020). No policy changes are warranted.

In 2022 we added the American Gastroenterology Association guidelines which further support the use of pH monitoring (Katz, 2022; Yadlapati, 2022). No new policy changes were warranted.

References

On May 4, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Esophageal pH Monitoring” (MeSH), “Gastroesophageal Reflux/classification” (MeSH), “Gastroesophageal Reflux/diagnosis” (MeSH), “esophageal pH monitoring,” and “reflux testing.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

6/2018: initial review date and clinical policy effective date: 8/2018

9/2019: Policy references updated.

8/2020: Policy references updated.

8/2021: Policy references updated.

8/2022: Policy references updated.