Clinical Policy Title: Esophageal pH monitoring

Clinical Policy Number: CCP.1381

Effective Date: August 1, 2018
Initial Review Date: June 5, 2018
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Related policies:

- CCP.1390 Upper gastrointestinal endoscopy
- CCP.1224 Anti-reflux devices for gastroesophageal reflux disease
- CCP.1090 Bariatric surgery for adults

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s 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 Prestige Health Choice 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. Prestige Health Choice’s 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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of 24-hour ambulatory esophageal catheter-based pH, wireless pH, or combined impedance-pH monitoring to be clinically proven and, therefore, medically necessary for the following indications (Rosen, 2018; Katz, 2013; Kahrilas, 2008):

- 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:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

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 (Rosen, 2018; Katz, 2013):
  • 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 treatment.
• Gastroenterology consultation.
• Esophagogastroduodenoscopy.
• Manometry.
• Barium contrast study.
• Scintigraphy.
• Fundoplication.
• 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 ensues when protective mechanisms of the upper digestive tract are impaired, resulting in insufficient clearance and buffering of refluxate, delayed gastric emptying, abnormalities in epithelial restitution and repair, or decreased neural protective reflexes of the aerodigestive tract. A consensus definition describes gastroesophageal reflux disease as 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).

Typical symptoms associated with gastroesophageal reflux disease 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.

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 (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).

**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 percent of the measured pH values are less than 4. However, normal pH results may not exclude a diagnosis of gastroesophageal reflux disease (InterQual, 2012).

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on April 27, 2018. Search terms were: “Esophageal pH Monitoring” (MeSH), “Gastroesophageal Reflux/classification” (MeSH), “Gastroesophageal Reflux/diagnosis” (MeSH), and the free text terms “esophageal pH monitoring” and “reflux testing.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic
reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**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).

The diagnostic accuracy of each monitoring type varies 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 cannot be determined based solely on these estimates, as each has its own benefits and limitations.

Compared to catheter-based pH monitoring, wireless pH monitoring is 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.

Evidence-based guidelines provide recommendations for reflux testing in adult (Katz, 2013; Kahrilas, 2008) and pediatric (Rosen, 2018; National Institute for Health and Care Excellence, 2015) 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.

Policy updates:

None.

Summary of clinical evidence:

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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Rosen (2018) for the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition Pediatric gastroesophageal reflux clinical practice guidelines | **Key points:**
| | ● For infants (ages 0 – 12 months) with frequent regurgitation and/or vomiting generally do not require diagnostic testing unless symptoms impact feeding, growth, or acquisition of developmental milestones.
| | ● Routine use of pH monitoring is not recommended for diagnosing gastroesophageal reflux disease, but may be used when impedance-pH monitoring is not available in some circumstances (indicated by an asterisk [*] below).
| | ● Recommended indications for multichannel impedance-pH testing are to:
| | – Correlate persistent troublesome symptoms with acid and non-acid gastroesophageal reflux events.*
| | – Clarify the role of acid and non-acid reflux in the etiology of esophagitis, eosinophilia, and other signs and symptoms suggestive for gastroesophageal reflux disease.*
| | – Determine the efficacy of acid suppression therapy.*
| Iluyomade (2017) Interference with daily activities and major adverse events during esophageal pH monitoring with Bravo wireless capsule versus conventional intranasal catheter | **Key points:**
| | ● Systematic review of three randomized controlled trials (167 adult patients).
| | ● The average age of enrolled patients was 51 years.
| | ● Interference with normal daily activities was greater in the catheter group than the Bravo group.
| | ● Significantly more overall adverse events in the catheter group than the Bravo group; mostly nasal and throat discomfort in catheter group versus more perceived chest pain in the Bravo group.
| National Institute for Health | **Key points:**
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  - Suspected recurrent aspiration pneumonia.
  - Unexplained apneas.
  - Unexplained non-epileptic seizure-like events.
  - Unexplained upper airway inflammation.
  - Dental erosion associated with a neurodisability.
  - Frequent otitis media.
  - A possible need for fundoplication.
  - Suspected diagnosis of Sandifer's syndrome.
  - Indication for an esophageal pH study without impedance monitoring is assessing effectiveness of acid suppression. |
| Kessels (2014) for the Medical Services Advisory Committee — Australia Catheter-free (wireless) ambulatory esophageal pH monitoring for gastro-esophageal reflux disease | **Key points:**
- Systematic review of 75 studies of variable designs and quality.
- Compared to catheter-based monitoring, catheter-free monitoring was associated with:
  - Significantly more chest pain, but less nose and throat pain, dysphagia, eating and drinking difficulties, headache, overall discomfort, and negative impact on normal daily activities; severe complications were rare.
  - Approximately three times the risk of having technical problems; the most commonly reported complication was early capsule detachment.
  - Comparable failure rates and recording efficacy.
  - More problems during insertion or placement (median 7.5% procedures, range 0% to 12%).
  - Inconclusive results on measurement of acid exposure time.
  - Significantly fewer reflux events detected.
  - Significantly higher diagnostic yield (p<0.001).
- Diagnostic accuracy of catheter-free monitoring: sensitivity 59% to 100% and specificity 66% to 100%, depending on cut-off values and reference standard used.
- Inconclusive evidence supporting change in management or improvement in outcomes based on test result. |
| van der Pol (2013) Diagnostic accuracy of tests in pediatric gastro-esophageal reflux disease | **Key points:**
- Systematic review of six studies with 408 total participants (ages 1 month – 13.6 years) and 145 controls (ages 1 month – 16.9 years) that assessed the diagnostic accuracy of pH monitoring (six studies), two of which included esophagogastroduodenoscopy (macroscopy and histology), compared with history and physical examination. No studies of pH-impedance, barium contrast study, scintigraphy, and empirical treatment as diagnostic tools met inclusion criteria.
- Nearly all studies of pH-metry 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.
- Overall quality: poor according to Quality Assessment of Studies of Diagnostic Accuracy Included in Systematic Reviews criteria.
- The range of reported sensitivity and specificity was broad and unreliable because of poor methodological quality (three studies). |
| Katz (2013) for the | **Key points:**

Citation | Content, Methods, Recommendations
---|---
American College of Gastroenterologists Guidelines for the diagnosis and management of gastroesophageal reflux disease | • Ambulatory reflux monitoring is the only test that can assess reflux symptom association (strong recommendation, low level of evidence).
• Reflux monitoring off medication can be performed by any available modality (pH or impedance-pH). (Conditional recommendation, moderate level of evidence.)
• Reflux testing on medication should be performed with impedance-pH monitoring to enable measurement of nonacid reflux. (Strong recommendation, moderate level of evidence.)
• Recommended indications (strong recommendation, low level of evidence):
  - Before surgical therapy in patients with non-erosive disease.
  - Patients who are refractory to proton pump inhibitors and negative evaluation by endoscopy (if presenting with typical symptoms) or evaluation by otolaryngologist, pulmonary, and allergy specialist (if presenting with extra-esophageal symptoms).
  - When the diagnosis of gastroesophageal reflux disease is in question.
• Not indicated in the presence of short or long-segment Barrett’s esophagus to establish a diagnosis of gastroesophageal reflux disease. (Strong recommendation, moderate level of evidence.)
• Can be considered before a proton pump inhibitor trial in patients with extra-esophageal symptoms who do not have typical symptoms of gastroesophageal reflux disease (Conditional recommendation, low level of evidence.)

Kahrilas (2008) for the American Gastroenterological Association Medical position statement on the management of gastroesophageal reflux disease | Key points:
• Recommended with fair evidence that it improves important outcomes:
  - Ambulatory impedance-pH, catheter pH, or wireless pH monitoring (proton pump inhibitor therapy withheld for seven days) to evaluate patients with a suspected esophageal gastroesophageal reflux disease syndrome who have not responded to an empirical trial of proton pump inhibitor therapy, have normal findings on endoscopy, and have no major abnormality on manometry.
  - Wireless pH monitoring has superior sensitivity to catheter studies for detecting pathological esophageal acid exposure because of the extended recording period (48 hours or more) and superior recording accuracy compared with some catheter designs.
• No recommendation or insufficient evidence to recommend for or against combined impedance-pH, catheter pH, or wireless pH esophageal monitoring studies:
  - To distinguish hypersensitivity syndromes from functional syndromes, the distinction being that in hypersensitivity syndromes symptoms are attributable to reflux events, whereas in functional syndromes they are not.
  - When performed while taking proton pump inhibitors.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations:**

None identified as of the writing of this policy.

**Local Coverage Determinations:**

None identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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