Clinical Policy Bulletin: Esophageal and Airway pH Monitoring

Number: 0667

Policy

I. Aetna considers esophageal pH monitoring medically necessary for any of the following indications:

A. To detect refractory reflux in members with chest pain after cardiac evaluation using a symptom reflux association scheme, preferably the symptom association probability calculation (pH study done after a trial of proton pump inhibitor [PPI] therapy for at least 4 weeks); or

B. To document abnormal esophageal acid exposure in an endoscopy-negative member being considered for surgical anti-reflux repair (pH study done after withholding anti-secretory drug regimen for more than 1 week); or

C. To document concomitant gastro-esophageal reflux disease (GERD) in an adult onset, non-allergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding anti-secretory drugs for more than 1 week). Note: a positive test does not prove causality; or

D. To evaluate a member with suspected otolaryngologic manifestations (chronic cough, laryngitis, pharyngitis) of GERD after symptoms have failed to respond to at least 4 weeks of PPI therapy (pH study done while the member continues taking their anti-secretory drug regimen to document the adequacy of therapy); or

E. To evaluate vomiting in infants up to 3 months of age; or

F. To evaluate members after anti-reflux surgery who are suspected to have ongoing abnormal reflux (pH study done after withholding anti-secretory drug regimen for more than 1 week); or
G. To evaluate members with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to PPI therapy (pH study done after withholding anti-secretory drug regimen for 1 week
or more if the study is done to confirm excessive acid exposure or while taking the anti-secretory drug regimen if symptom-reflux correlation is to be scored).

The disposable capsule pH monitor (Bravo pH Monitoring System) is considered an acceptable alternative to standard catheter-based ambulatory pH monitoring for the medically necessary indications listed above except for evaluating vomiting for infants. The Bravo pH Monitoring System is considered experimental and investigational for evaluating vomiting in infants because it has not been approved for use in this age group.

II. Aetna considers esophageal pH recording experimental and investigational for all other indications, including any of the following indications because its effectiveness for these indications has not been established:

A. To detect or verify reflux esophagitis in adults (this is an endoscopic diagnosis); or
B. To evaluate “alkaline reflux” in adults; or
C. To titrate PPI dosing in the management of Barrett's esophagus.

III. Aetna considers airway pH monitoring for detection of laryngo-pharyngeal reflux and other indications experimental and investigational because its effectiveness for these indications has not been established.

IV. Aetna will consider coverage for multichannel intraluminal pH impedance testing for evaluation of GERD in pediatric members on a case by case basis.

V. Aetna considers multichannel intraluminal impedance in the evaluation of GERD in adolescents and adults experimental and investigational because there is inadequate evidence in the peer-reviewed published clinical literature regarding its effectiveness.

Background

Esophageal pH recording provides quantitative data on both esophageal acid exposure and on the correlation between patient symptoms and reflux events. Despite these strengths, the inherent weakness of the technique is its inability to prove causality between symptoms and acid reflux. Alternatively, causality is reasonably assumed in clinical practice by the alleviation of suspected reflux symptoms during a therapeutic trial of a proton pump inhibitor (PPI). In view of this viable alternative, the AGA (2001) has concluded that the major indications for esophageal pH monitoring are in documenting the failure of either medical or surgical therapy.

For standard ambulatory esophageal pH monitoring, a nasogastric catheter fitted with a pH probe is inserted through the nose into the lower esophagus. The
catheter is attached to a data logger that is worn on the body. The catheter is left in place for 24 to 48 hrs. Over this period, the probe measures the amount of acid refluxing in the esophagus and the pattern of occurrence throughout the day. The patient reports any symptoms, such as pain, waterbrash, wheezing and coughing, and their timing. Some ambulatory pH monitors have a button for the patient to press when he/she is having symptoms in order to alert the physician reading the study that they were having symptoms at a particular time. This helps the physician to determine if symptoms are related to acid reflux.

Because the use of a nasogastric catheter is awkward and distressing to the patient, a newer catheter-free approach has been developed (the Bravo pH Monitoring System, Medtronic, Minneapolis, MN) that uses a tiny disposable capsule pH monitor that is pinned to the lower esophagus via an endoscopic approach. The capsule transmits pH data to a data logger that is worn on the body. After several days, the disposable capsule is sloughed off the esophagus and passes out of the digestive tract.

An assessment of the evidence supporting catheterless esophageal pH monitoring by the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that “[c]urrent evidence on the safety and efficacy of catheterless oesophageal pH monitoring appears adequate to support the use of this technique provided that normal arrangements are in place for consent, audit and clinical governance.” The assessment noted that catheterless pH monitoring would be particularly appropriate in children and other patients who may not tolerate the nasal intubation required for catheter-based monitoring. The assessment also noted that catheterless pH monitoring may be unsuitable for some patients, for example patients with pacemakers.

Dickman and Fass (2006) stated that "pH testing remains a commonly used evaluative tool in clinical practice. However, the original tool that included a nasally placed pH catheter was plagued with a variety of shortcomings, primarily the effect of the procedure on patients' lifestyle and thus on reflux-provoking activities. The miniaturization of evaluative techniques in gastroenterology was the impetus for the development of the wireless pH capsule and the SmartPill. These modalities improve patients' tolerability of the required test and provide a unique opportunity for expansion of indications and data collection. The introduction of the multi-channel intraluminal impedance with a pH sensor allowed the detection of gastroesophageal reflux (GER) that is non-acidic. However, the value of the technique beyond the realm of academic gastroenterology remains to be elucidated. Recently, there was a renewal of interest in Bilitec 2000. The technique, which has never found a clear clinical role, has been recommended as an important tool in evaluating patients who failed PPI therapy. However, data to support its clinical value in this situation have remained scant".

Wenner et al (2007) evaluated and compared the subjective experience of patients undergoing esophageal pH monitoring by means of the wireless pH capsule method or the conventional catheter-based method. Using a randomized study design, patients referred for esophageal pH testing underwent both wireless and traditional catheter-based 24-hr pH recording with a 7-day interval. The wireless pH capsule was placed during endoscopy and followed by 48-hr pH recording. All patients answered a questionnaire, including a 10-cm visual analog scale (VAS),
which described the perceived severity of symptoms and the degree of interference with normal daily activities during the pH tests. A total of 31 patients (16 women and 15 men) were included in the analysis. The severity of all adverse symptoms associated with the wireless technique was significantly lower compared with the catheter-based technique (median VAS 2.1 versus 5.1, p < 0.001). Wireless pH recording was associated with less interference with off-work activities and normal daily life, median VAS 0.6 and 0.7 compared with 5.0 and 5.7, respectively, for the catheter-based technique (p < 0.0001). Patients actively working during both tests reported less interference with normal work during the capsule-based test than during the catheter-based pH test (median VAS 0.3 versus 6.8, p = 0.005). Twenty-seven patients (87%) stated that, if they had to undergo esophageal pH monitoring again, they preferred the wireless test over the catheter-based pH test (p < 0.0001). The authors concluded that these findings showed that a significant majority of patients undergoing esophageal pH monitoring preferred the wireless pH capsule over the traditional catheter-based technique because of less adverse symptoms and less interference with normal daily life.

Davids and colleagues (2008) stated that laryngo-pharyngeal reflux (LPR) -- GER above the upper esophageal sphincter -- is a common problem encountered by otolaryngologists. Despite consensus guidelines, the presentation, diagnosis, and treatment remain controversial. These researchers surveyed Canadian otolaryngologists to assess current perspectives. Web-based questionnaires were e-mailed to 135 otolaryngologists. Respondents were categorized by subspecialty as head and neck (H&N) or non-H&N (rhinology, otology, laryngology, facial plastics, general and pediatric otolaryngology). Data were analyzed to determine differences in proportions between groups. The response rate was 48 of 135 otolaryngologists. Symptoms considered to be strongly or moderately associated with LPR included globus sensation, excessive throat clearing, sore or burning throat, hoarseness, chronic cough, and dysphonia. The laryngoscopic signs considered strongly associated with LPR were edema, intra-arytenoid changes, and granulomata. The majority of otolaryngologists in both the H&N (12 of 15) and non-H&N groups (27 of 32) use flexible laryngoscopy for investigation and diagnosis of LPR. Proton pump inhibitors in addition to lifestyle modifications are recommended by both groups as 1st- and 2nd-line therapy for an initial course of 6 to 12 weeks, with long-term therapy extended for 4 to 12 months. The authors concluded that Canadian otolaryngologists do correlate specific signs and symptoms with LPR patients. This is consistent across sub-specialties within the field. Flexible fibre-optic laryngoscopy is the preferred diagnostic tool. Although evidence based on randomized controlled trials has yet to demonstrate a reproducible, statistically significant improvement in LPR from treatment, 1st-line pharmacotherapy (in addition to lifestyle changes) is generally provided as a PPI, with the duration of therapy being somewhat variable and less than that recommended by the current literature.

Mel-S (2008) stated that LPR is a a widely recognized disorder in otolaryngological practice. However, the signs and symptoms attributed to this disorder are non-specific and treatment is usually empirical. The author noted that there is still much to learn about the pathophysiological mechanisms of LPR and there is still much controversy on diagnostic as well as therapeutic parameters for this condition. There is no consensus on the diagnosis and treatment of LPR and the
majority of clinicians depend mainly on clinical findings and empirical treatments rather than more specific investigations. The author concluded that the concept of LPR is still controversial. The current practice of empirical treatment with PPIs is based on weak evidence. However, this practice seems to be widely accepted and will not change until further clinical and laboratory studies improve the understanding of this condition.

Gupta and Sataloff (2009) shared the same view on LPR as Mel-S (2008). These investigators noted that despite numerous research efforts, the diagnosis and treatment of LPR remain elusive and unproven. Acid-induced changes in laryngopharyngeal mucosa have been confirmed by histological evidence. However, the implications of this for laryngeal signs and symptoms are unclear. Diagnosis remains controversial, confounded by a lack of standardization and accepted evidence-based norms. Whereas treatment is generally believed by clinicians to be effective in alleviating signs and symptoms attributed to LPR, incontrovertible data confirming efficacy are scarce. Confounding the issues further, there are numerous studies that purport to show that various widely used treatments are not effective, although the scientific merit of virtually all of these studies has been challenged. The authors concluded that LPR remains a controversial diagnosis. Treatment with PPIs persists despite weak evidence supporting or refuting their utility, and well-designed studies are needed to understand diagnosis, treatment, pathophysiology, and long-term health consequences of LPR and its treatment.

DiFiore et al (2005) examined the temporal relationship between apnea and gastroesophageal reflux (GER) and assessed the effect of GER on apnea duration. A total of 119 preterm infants underwent 12-hour cardiorespiratory monitoring studies using respiratory inductance plethysmography, heart rate, oxygen saturation (SaO2), and esophageal pH. The studies were scored for GER (pH less than 4 for greater than or equal to 5 seconds) and apnea greater than or equal to 15 seconds or greater than or equal to 10 seconds that occurred within 30 seconds of GER. Apnea greater than or equal to 10 seconds was used to assess whether GER would prolong apnea duration. There were a total of 6,255 episodes of GER. Only 1 % of GER episodes were associated with apnea greater than or equal to 15 seconds, and there was no difference in apnea rate before, during, or after GER. There was also no difference in rate of apnea greater than or equal to 10 seconds before versus during GER; however, there was a decrease in apnea rate immediately after GER. The presence of GER during apnea did not prolong apnea duration, and GER had no effect on the lowest SaO2 or heart rate during apnea. The authors concluded that there is no evidence of a temporal relationship between acid-based GER and apnea in preterm infants. In addition, GER does not prolong apnea duration and does not exacerbate the resultant decrease in heart rate and SaO2. Moreover, the 2006 summary proceedings from the Apnea Prematurity Group of the National Institutes of Child Health and Human Development (Finer et al, 2006) termed the relationship between apnea of prematurity (AOP) and GERD unsubstantiated.

Slocum et al (2007) stated that GER and AOP are both common occurrences in premature infants. However, a causal relationship between the 2 remains controversial. Strong physiologic evidence indicates that a variety of protective reflex responses may elicit laryngeal adduction and apnea. Although a potential link between GER and apnea may exist through this pathway, clinical studies can
be cited to either support or refute such a link in premature infants. The majority of GER episodes do not appear to be related to apnea. In a specific subset of events, a causal relationship may exist. Whether this is related to the character of the reflux episode or to a predisposition in a subpopulation of infants is unclear. The authors presented the evidence for and against an association between GER and apnea, discussed techniques used in their evaluation, and identified approaches for future investigation.

Corvaglia et al (2009) evaluated the relationship between GER detected by combined multi-channel intraluminal impedance-pH measurement and AOP in 26 preterm infants. Although the findings showed that 154 apneas out of 1,136 were triggered by GER (p = 0.034), the authors concluded that further studies are needed to recognize clinical features that identify those patients who are more susceptible to GER-triggered apneas.

The American College of Radiology's Appropriateness Criteria on "Vomiting in infants up to 3 months of age" (Bulas et al, 2011) stated that "The role of imaging in evaluating the vomiting infant is to define whether and where there is a point of anatomic obstruction. Secondarily, one should note whether there is GER or delayed gastric emptying. Diagnostic studies that are complementary to imaging examinations include esophageal pH monitoring, esophageal motility studies, endoscopic evaluation of the esophagus, and multichannel intraluminal impedance".

The AGA's medical position statement on the management of Barrett's esophagus (2011) noted that "The guideline developers recommend against attempts to eliminate esophageal acid exposure (proton pump inhibitors [PPIs] in doses greater than once daily, esophageal pH monitoring to titrate PPI dosing, or antireflux surgery) for the prevention of esophageal adenocarcinoma (strong recommendation, moderate-quality evidence)".

Multichannel Intraluminal Impedance (MII) technology was designed to allow characterization of bolus movement within the esophagus regardless of the pH level. It provides 2 testing modalities in the evaluation of GERD. Esophageal function testing (EFT) combines MII with standard pressure manometry. Gastroesophageal reflux (GER) monitoring (Sleuth) combines MII with standard pH testing. Combined manometry and impedance is intended to provide an assessment of esophageal function without the need for radiation. MII with pH is intended to determine whether a patient has non-acid reflux and help to determine why a patient continues to have symptoms while on adequate medical therapy. It also is intended to sort out which patients with continuing symptoms on medical therapy do not have reflux as the cause of their symptoms. Multichannel intraluminal impedance in combination with pH monitoring in the evaluation of GERD is considered investigational/experimental because there is inadequate evidence in the peer-reviewed published clinical literature regarding its effectiveness.

An AHRQ assessment on the management of gastroesophageal reflux disease (Ip, et al., 2011) concluded: "There is a lack of consensus among clinical practitioners around the issue of selecting the best diagnostic method to use, and its timing, in identifying acid and nonacid reflux during symptomatic episodes. The
role of newer methods, such as impedance monitoring, needs to be examined in terms of impact in the areas of diagnosis and treatment."

A technology assessment of impedance monitoring in GERD by the Centre for Evidence-based Purchasing (Talboys, et al., 2010) found the evidence for impedance monitoring to be inconclusive: "Although there is some evidence to support the use of MII-pH measurements, the quality of the studies is generally poor. Most of the studies do not have any case controls and there is variation between studies in the equipment and criteria used for assigning patients into different sub-groups. High quality studies are required to determine the optimum testing protocol, on or off therapy. Only one poor quality study discussed the outcome of changing patient management following MII-pH investigation. At present the evidence is inconclusive for the use of MII-pH devices in patients with persistent symptoms while being treated for GORD."

An American Gastroenterology Association technical review on the management of GERD (Kahrilas, et al., 2008) stated: "Very little of the literature focused on testing management strategy trials but rather tended to demonstrate the capabilities of new technologies without rigorously testing the clinical validity of the result. This was especially true of impedance monitoring where, despite the large number of citations, there were no high-quality outcome trials. Hence, there was only one B-level recommendation regarding the reflux testing methodologies and it failed to distinguish among them; with respect to the unique capabilities of impedance monitoring, only an 'I' level recommendation could be made."

A guideline on surgical treatment of gastroesophageal reflux disease by the Society of American Gastrointestinal and Endoscopic Surgeons (2010) stated: "Based on the available evidence, the diagnosis of gastroesophageal reflux disease (GERD) can be confirmed if at least one of the following conditions exists: a mucosal break seen on endoscopy in a patient with typical symptoms, Barrett's esophagus on biopsy, a peptic stricture in the absence of malignancy, or positive pH-metry (Grade A). A newer test to objectively document gastroesophageal reflux is multichannel intraluminal esophageal impedance but the available evidence is insufficient to provide firm recommendations."

A critical review of esophageal impedance monitoring by Herbella (2012) found a lack of evidence for clinical utility of esophageal impedance measurements: "MII made great contributions for the understanding of esophageal physiology; however, direct clinical applications are few. MII-pH was expected to identify patients with normal acid reflux and abnormal nonacidic reflux. Unfortunately, these patients are rarely found off therapy, that is, nonacidic reflux parallels acid reflux; and the significance of isolated nonacidic reflux is unclear. Repeating words by Sifrim and Zerbib: 'Combined pH-impedance has little added value in patients 'off' therapy and virtually no outcome data exist to determine the optimal pH-impedance parameters.' The significance of bolus transit is elusive. MII-manometry findings that contradicts manometry lacks better understanding and clinical implication."

Guidelines from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (Vandenplas, et al., 2009) indicated the use of multichannel intraluminal esophageal impedance with pH monitoring for
evaluation of the temporal relation between symptoms and gastroesophageal reflux in children. In children, pHMII is useful to correlate symptoms with reflux (particularly nonacid reflux), to quantify reflux during tube feedings and the postprandial period, and to assess efficacy of antireflux therapy."

Frohlich et al (2008) conducted a study in 24 patients aged 4 months to 23 years to evaluate GERD and its association with gastrointestinal or extraintestinal symptoms using combined multichannel intraluminal impedance and pH measurement. The 24 hour multichannel intraluminal impedance and pH measurement evaluation was performed with a single catheter comprised of 6 impedance channels and 1 pH channel. The authors detected a total of 911 episodes of retrograde bolus movement, including 379 acidic and 532 weakly acidic bolus movements. Of the 201 symptom events recorded, 42% were associated with retrograde bolus movements, 24% with weakly acidic reflux, and 16% with acid reflux episodes. Esophageal atresia patients showed significantly fewer complete swallows of liquid than patients without esophageal surgery (42% vs 98%). The authors concluded that in patients with corrected esophageal atresia, half of the reflux events could be detected only by multichannel intraluminal impedance and that weakly acidic reflux can be responsible for the patients' symptoms. However, the authors also noted that patients may have few or no symptoms despite poor esophageal function and extensive GERD.

Di Pace et al (2011) described the use of impedance measurements in healthy children and in a pediatric population with GERD. The authors evaluated 60 children who submitted to multichannel intraluminal impedance pH monitoring for 24 hours for suspected GERD. The results showed that patients fell into two groups, one being acid GERD and a second group which had negative multichannel intraluminal impedance pH monitoring analysis for GERD, despite being symptomatic. The group showing acid GERD had a median mean acid clearing time of 151 seconds and a median mean bolus clearing time of 25 seconds. The group which was negative per the multichannel intraluminal impedance pH monitoring analysis had normal values. The authors concluded that multichannel intraluminal impedance pH monitoring is "an ideal test in children because it studies GER[D] with its characteristics and motility pattern."

Catalano et al (2011) evaluated 22 children treated for esophageal atresia at birth and 20 normal children of similar age with suspected GERD using multichannel intraluminal impedance and pH measurement. The goal of the study was to evaluate characteristics of GERD and esophageal clearance in children treated for esophageal atresia with distal tracheoesophageal fistula. A significant difference was found between the two groups, with the median mean bolus clearing time and mean acid clearing time longer in the esophageal atresia group. Thus, the investigators concluded that the incidence of GERD may be underestimated if pH-metry is used and that the pH multichannel intraluminal impedance is an ideal test in children because it studies GERD both for its characteristics and its motility pattern.

Salvatore et al (2013) analyzed the age effect on impedance baseline in multichannel intraluminal impedance testing in a large population of pediatric patients. A total of 816 children with GERD symptoms were evaluated using multichannel intraluminal impedance testing, with mean impedance baseline
automatically calculated in the different multichannel intraluminal impedance channels through 24 hour tracings. Mean impedance baseline was significantly lower in younger compared with older children up to 48 months (P < 0.001). The mean increase of impedance baseline per month was 2.9 in the group positive for multichannel intraluminal impedance testing and 2.3 in the group with normal tested values. From 48 months onward, there was no significant difference between the two groups. The authors concluded that impedance baseline is significantly lower in infants compared with older children and that low impedance baseline in both the proximal and distal esophagus in young infants may be related to anatomical and functional differences due to etiologies other than the presence of esophagitis.

CPT Codes / HCPCS Codes / ICD-9 Codes

**Esophageal pH Monitoring:**

**CPT codes covered when selection criteria are met:**

91034

91035

**ICD-9 codes covered if selection criteria are met:**

462 Acute pharyngitis

464.00 Acute laryngitis without mention of obstruction

472.1 Chronic pharyngitis

476.0 Chronic laryngitis

493.10 Intrinsic asthma, unspecified

530.81 Esophageal reflux

786.2 Cough

786.50 Chest pain, unspecified

**ICD-9 code not covered for indications in the CPB:**

530.11 Reflux esophagitis

530.85 Barrett's esophagus

536.2 Persistent vomiting [vomiting in infants]

770.81 - Primary and other apnea of newborn

770.82

779.2 - Bilious and other vomiting in newborn

779.33
787.01 Nausea with vomiting [vomiting in infants]
787.03 Vomiting alone
787.04 Bilious emesis [vomiting in infants]

Airway pH Monitoring:

There is no specific code for airway pH monitoring:

Multichannel intraluminal impedance in combination with pH monitoring:

No specific code

CPT codes not covered for indications in the CPB:

91037
91038

ICD-9 codes not covered for indications listed in the CPB:

530.81 Esophageal reflux

The above policy is based on the following references:


