I. Description

Gastroesophageal reflux disease (GERD) is caused by the return of stomach contents into the esophagus. This can cause heartburn from irritation of the esophagus by stomach acid. GERD can lead to scarring and stricture of the esophagus and some patients will progress to more serious conditions.

Catheter-based esophageal monitoring to diagnose GERD uses a tube with a pH electrode attached to its tip that is passed through the nose and positioned in the esophagus five centimeters above the manometrically defined upper limit of the lower esophageal sphincter. The electrode is attached to a data logger worn on a waist belt or shoulder strap. Every instance and duration of acid reflux is recorded as well as the pH level indicating gastric acid reflux over a 24-hour period.

A catheter-free, temporarily implanted device (Bravo pH Monitoring System, Medtronic) uses endoscopic or manometric guidance as the capsule is temporarily implanted in the esophageal mucosa using a pin. The capsule records pH levels up to 96 hours and transmits them by radiofrequency telemetry to a receiver worn on the patient’s belt. Data from the recorder are uploaded to a computer for analysis.

Another technology closely related to pH monitoring is impedance-pH monitoring, which incorporates pH monitoring with measurements of impedance, a method of measuring reflux of liquid or gas of any pH. Multiple electrodes are placed along the length of the esophageal catheter. The impedance pattern detected can determine the direction of flow and the substance (liquid or gas). Impedance monitoring is able to identify reflux events in which the liquid is only slightly acidic or non-acidic.

II. Criteria/Guidelines

A. Esophageal pH monitoring using a catheter-based or catheter-free, wireless system is covered (subject to Administrative Guidelines) for one or more of the following indications for adults and adolescents or children able to report symptoms:
1. Reflux symptoms that are refractory to proton pump inhibitor therapy in patients with either normal or equivocal endoscopic findings.
2. To establish a quantitative baseline measurement of reflux in patients anticipating anti-reflux surgery.
4. To evaluate suspected reflux in patients with chest pain after a negative cardiac evaluation and after a one-week trial of proton pump inhibitor therapy at therapeutic dose.
5. Suspected otolaryngologic manifestations of GERD (i.e., laryngitis, pharyngitis, chronic cough) that have failed to respond to proton pump inhibitor therapy.
6. Concomitant GERD in an adult-onset, nonallergic asthmatic suspected of having reflux-induced asthma.

B. Esophageal pH monitoring is covered (subject to Administrative Guidelines) for infants or children who are unable to report or describe symptoms of reflux, and have any of the following:
   1. Unexplained apnea
   2. Bradycardia
   3. Refractory coughing or wheezing, stridor, or recurrent choking (aspiration)
   4. Persistent or recurrent laryngitis
   5. Recurrent pneumonia

C. Esophageal pH monitoring systems should be used in accordance with FDA-approved indications and age ranges.

III. Administrative Guidelines

A. Precertification is not required for this service. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and must be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

B. Manometry, when used for pH tip placement, is considered part of the pH recording and will not be paid separately.

C. The device may be placed with either endoscopic or manometry guidance. CPT codes 43235 (endoscopy) or 91010 (manometry) might be used, followed on a subsequent day with the code 91034 (nasal catheter) or 91035 (Bravo esophageal pH monitoring), which represents the interpretation of the recorded measurements.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>91034</td>
<td>Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation</td>
</tr>
<tr>
<td>91035</td>
<td>with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation</td>
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IV. Scientific Background

Esophageal pH monitoring for 24 hours using catheter-based systems has been an established technology, primarily used in patients with gastroesophageal reflux disease (GERD) that has not responded symptomatically to a program of medical therapy (including proton pump inhibitors [PPIs]) or in patients with refractory extra-esophageal symptoms. Although it is an established technology, its use as a diagnostic test for GERD are problematic and thus make it difficult to determine its utility, as well as the utility of potential alternative tests.

There is no independent reference standard for GERD for certain clinically relevant populations. Traditional pH monitoring has been evaluated in patients with endoscopically diagnosed GERD, where it has been shown to be positive 77-100% of the time. However, in clinically defined but endoscopically negative patients, the test is positive from 0-71% of the time. In normal control populations, traditional pH monitoring is positive in 0-15% of subjects. Thus the test is imperfectly sensitive and specific in patients with known presence or absence of disease. The state of this evidence regarding the diagnostic capability of catheter-based pH monitoring led the authors of this technical review “…to conclude that ambulatory pH studies quantify esophageal acid exposure but that this has an imperfect correlation with reflux-related symptoms, esophageal sensitivity, or response to acid suppressive therapy.”

Without a reference standard for GERD, it is difficult to compare diagnostic test performance between different types of tests. It is possible to determine whether 2 tests correspond close enough that they might be considered equivalent tests. Use of one test versus another may result in better patient outcomes, if despite being an imperfect test, differences in patient management based on the test results result in overall improved patient outcomes. However, this type of argument would require rigorous studies that follow patients beyond test outcome and are organized and analyzed such that a valid inference of improved outcome due to the use of the test can be made.

Wireless pH Monitoring

A 2006 TEC Special Report on wireless esophageal monitoring made several observations regarding wireless pH monitoring. Six case series demonstrated high success rates in successfully performing the procedure, with success rates over 90% in achieving a 48-hour pH study. Two studies that surveyed patients who received wireless pH monitoring and patients who received traditional catheter monitoring showed less discomfort, less disruption of daily activities, and higher overall satisfaction with the experience. Studies that evaluated test positivity in clinically diagnosed GERD cases and normal controls showed similar results as have been reported in such patients using traditional pH monitoring. Studies directly comparing the performance between traditional catheter and wireless pH monitoring in the same patients showed a correlation
between the two types of studies after correcting for calibration differences. The ideal cut-point for test positivity was different for the two types of tests.

Some studies attempted to support an argument that the longer monitoring time that the wireless monitor allows results in superior test performance. However, without a reference standard, or showing superior patient outcomes based on the longer test, such an argument cannot be made. The longer monitoring period usually results in a larger proportion of tests that are classified as positive, depending on the method of determining a positive test. As reviewed in the 2006 TEC Special Report, Prakash and Clouse compared the diagnostic yield for a single day of monitoring compared to the complete 2 days of monitoring. The authors reported that the second day of recording time increased the number of subjects recording symptoms by 6.8%. However, this study had several methodologic flaws. Ideally, a study comparing the diagnostic performance of an additional day of monitoring would require an independent reference standard or demonstration of improved patient outcomes when managing patients with a 1-day versus a 2-day study. In this study, the 2-day study was essentially considered the “reference test,” and there was no discussion of how the second day of monitoring was used to improve patient management in this heterogeneous group of patients. In addition, in their statistical analysis, the authors eliminated patients who did not report any symptoms during the testing period, thus deflating the denominator and inflating the yield of the additional day of testing. Finally, the 1-day test was essentially a component of the 2-day test, and thus the 2 monitoring periods were not independent, further limiting any comparison between them. It should not be presumed that the greater number of positive tests produced by a longer duration of test is evidence of a superior test.

Studies published since the 2006 TEC Special Report essentially show similar types of findings regarding the correlation of wireless pH monitoring and standard catheter monitoring. Wenner and colleagues, in another study of 64 patients with GERD and 50 asymptomatic controls, showed a sensitivity of 59–65%, when setting the specificity to 90–95%. This was noted to be worse than other studies of traditional pH monitoring, but the patient population may have had less severe disease. The study by Schneider and colleagues showed similar diagnostic performance of wireless and traditional pH monitoring. Hakanson and colleagues evaluated simultaneous wireless and traditional pH testing in 92 patients. Wireless pH testing showed consistently lower estimates of acid exposure than traditional pH testing. The two techniques were correlated (r-squared=0.66); however, the range between limits of agreement was wide. The two techniques were concordant regarding the final diagnosis 82.1% of the time.

Additional studies since the 2006 TEC Special Report also repeat the findings that a longer period of monitoring increases the proportion of positive tests. Scarpulla and colleagues attempted 96-hour monitoring in 83 patients. Monitoring for the full 96 hours was successful in 41% of patients. In these patients, the proportion showing some degree of pathologic acid exposure increased as the time of monitoring increased. Garrean and colleagues studied the use of 96-hour pH testing where during the first 2 days of monitoring, the patients were off therapy, and during the second 2 days, the patients were prescribed PPIs. As expected, during the second 2 days, fewer patients showed reflux symptoms. It is difficult to determine from the analysis of data how such a testing protocol improves the diagnosis of GERD. Grigolon and colleagues showed that in 51 patients receiving prolonged monitoring, the 96-hour test reduced the number of indeterminate tests
from 11 to 5. In this particular study, comparison of outcomes of patients receiving wireless monitoring and a matched control group of patients receiving traditional catheter monitoring showed similar outcome and satisfaction.

**Impedance-pH Testing**

Evidence supporting the use of impedance-pH testing suffers from similar issues as the evaluation of wireless pH testing; lack of a reference standard and lack of evidence showing improved patient outcomes. Many studies use the argument that an increase in positive tests, or diagnostic yield as it is called, by itself is evidence that supports the use of the test. However, the increase in positive tests, if it is reflective of a potentially increased sensitivity, may be accompanied by a decrease in specificity. The net effect on patient management and patient outcomes is not certain.

Several studies have demonstrated a higher yield of positive tests when using impedance-pH testing and identifying reflux events that are non- or only weakly acidic (and thus would not be detected using pH testing alone). Bajbouj and colleagues studied 41 patients with atypical GERD symptoms with numerous tests. The test that produced the highest number of positive findings was impedance-pH testing. Bredenoord and colleagues did a similar study in 48 patients. A higher proportion of subjects had positive tests when using impedance-pH data than when using pH data alone (77% vs. 67%, respectively). A study by Mainie and colleagues showed similar findings.

Studies have examined the issue of performing impedance-pH testing while the patient is currently on acid suppression therapy. Vela and colleagues demonstrated that during acid suppressive therapy, the total number of reflux episodes is similar, but there are fewer episodes of acidic reflux.

V. **Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
VI. References


