

## Corporate Medical Policy

### Esophageal pH Monitoring

<b>File Name:</b>	esophageal_ph_monitoring
<b>Origination:</b>	4/2011
<b>Last CAP Review:</b>	4/2012
<b>Next CAP Review:</b>	4/2013
<b>Last Review:</b>	4/2012

#### Description of Procedure or Service

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Acid reflux is the cause of heartburn and acid regurgitation peptic esophagitis, as well as esophageal stricture, some cases of asthma, posterior laryngitis, chronic cough, dental erosions, chronic hoarseness, pharyngitis, subglottic stenosis or stricture, nocturnal choking, and recurrent pneumonia. Gastroesophageal reflux disease (GERD) is usually diagnosed by clinical history and endoscopy, and is treated empirically with a trial of medical management.

Esophageal monitoring is done through the use of a tube with a pH electrode attached to its tip, which is then passed to almost exactly 5 cm above the upper margin of the lower esophageal sphincter (LES). The electrode is attached to a data logger 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. A catheter-free, temporarily implanted device (Bravo™ pH Monitoring System, Medtronic) has been cleared for marketing by the U.S. Food and Drug Administration (FDA) 510(k) process for the purposes of esophageal monitoring. Using endoscopic or manometric guidance, the capsule is temporarily implanted in the esophageal mucosa using a clip. The capsule records pH levels for up to 96 hours and transmits them via radiofrequency telemetry to a receiver worn in the patient's belt. Data from the recorder are uploaded to a computer for analysis by a nurse or doctor.

Another technology closely related to pH monitoring is impedance-pH monitoring, which incorporates pH monitoring with measurement 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.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**BCBSNC will provide coverage for esophageal pH monitoring when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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## When esophageal pH monitoring is covered

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Esophageal pH monitoring using a catheter-based system may be considered medically necessary for the following clinical indications in adults and children or adolescents able to report symptoms:

- Documentation of abnormal acid exposure in endoscopy-negative patients being considered for surgical antireflux repair,
- Evaluation of patients after antireflux surgery who are suspected of having ongoing abnormal reflux,
- Evaluation of patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy,
- Evaluation of refractory reflux in patients with chest pain after cardiac evaluation and after a 1-month trial of proton pump inhibitor therapy,
- Evaluation of suspected otolaryngologic manifestations of GERD (i.e., laryngitis, pharyngitis, chronic cough) that have failed to respond to at least 4 weeks of proton pump inhibitor therapy,
- Evaluation of concomitant GERD in an adult-onset, nonallergic asthmatic suspected of having reflux-induced asthma.

24-hour catheter-based esophageal pH monitoring may be considered medically necessary in infants or children who are unable to report or describe symptoms of reflux with:

- unexplained apnea;
- bradycardia;
- refractory coughing or wheezing, stridor, or recurrent choking (aspiration);
- persistent or recurrent laryngitis; and
- recurrent pneumonia.

48- to 96-hour, catheter-free, wireless esophageal monitoring may be considered medically necessary for use in esophageal pH monitoring for patients who are unable to tolerate catheter-based testing (and unable to complete this testing), but meet the criteria listed above for monitoring.

## When esophageal pH monitoring is not covered

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48- to 96-hour, catheter-free, wireless esophageal monitoring is considered not medically necessary for use in esophageal pH monitoring, except under the specific circumstances noted in the policy statement above.

24-hour catheter-based impedance-pH monitoring is considered not medically necessary.

## Policy Guidelines

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The American Gastroenterological Association released a medical position statement and accompanying technical review on the management of GERD in 2008. Ambulatory impedance-pH, catheter pH, and wireless pH monitoring were all supported as methods to evaluate patients with suspected GERD with otherwise normal endoscopy and no response to proton pump inhibitor therapy. The guideline is classified as a “Grade B” recommendation, denoting fair evidence that the practice improves health outcomes. The guideline additionally states that the wireless pH monitor has superior sensitivity to catheter pH monitoring because of the extended period of recording.

However, an increase in positive tests has been documented in other reports as producing both increased sensitivity and decreased specificity relative to the reference standard used in the particular study. Thus, taking into account both characteristics of diagnostic performance, it is unknown as to whether patient outcomes are improved.

In summary, given the lack of a gold standard for the diagnosis of GERD, there are still questions about the use of the wireless device in diagnosis and treatment. An increase in positive tests, at least in part due to the longer duration of wireless testing, has been documented in reports as producing both increased

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sensitivity and decreased specificity relative to the reference standard used in the particular study. Thus, taking into account both characteristics of diagnostic performance (sensitivity and specificity); it is unknown as to whether patients outcomes are improved. Other than patient comfort during the period of testing, the published literature does not demonstrate an advantage of the wireless pH monitoring compared to conventional catheter-based esophageal pH monitoring in managing patients or improving patient outcomes. Thus, use of the wireless device may be considered medically necessary in patients who meet criteria for testing but are unable to complete catheter-based testing due to inability to tolerate the system. For all other scenarios, use of the wireless device is considered not medically necessary.

## **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.

In summary, although impedance-pH testing produces a higher number of positive tests, particularly when compared to traditional or wired pH testing in the setting of concurrent acid suppressive therapy, there is insufficient evidence that these test results are more accurate, nor is there is clear link to improved patient outcomes when using impedance-pH testing when compared to other methods of measuring pH. Thus, this testing is considered not medically necessary.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 91034, 91035, 91038*

*Manometry, when used for pH tip placement, should be considered part of the pH recording.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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Kahrilas PJ, Shaheen NJ, Vaezi MF et al. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. *Gastroenterology* 2008; 135(4):1383-1391.

Kahrilas PJ, Shaheen NJ, Vaezi MF. American Gastroenterological Association Institute technical review on the management of gastroesophageal reflux disease. *Gastroenterology* 2008; 135(4):1392-1413.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 3/11/2010

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Wireless Esophageal pH Monitoring. TEC Assessments 2006; Volume 21, Tab 2

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 4/14/2011

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Medical Director review – 10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.20, 10/4/2011

Specialty Matched Consultant Advisory Panel 4/18/12

## Policy Implementation/Update Information

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| 5/10/11 | New policy developed. BCBSNC will provide coverage for esophageal pH monitoring when it is determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)                           |
| 11/8/11 | Description section updated to include information regarding impedance-pH monitoring. The following statement was added to the Not Covered section: “24-hour catheter-based impedance-pH monitoring is considered not medically necessary.” Billing/Coding section and Policy Guidelines updated. (adn) |
| 5/1/12  | CPT code 91037 removed from policy as it is not a monitoring code. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)   |

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.