Clinical Review Criteria
Capsule PH Monitoring System for Diagnosis Gastro-Esophageal Reflux Disease (GERD)

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Criteria
For Medicare Members

<table>
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<tr>
<th>Source</th>
<th>Policy</th>
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<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>24-Hour Ambulatory Esophageal pH Monitoring (100.3)</td>
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<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<td>Local Coverage Article</td>
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For Non-Medicare Members

The disposable capsule pH monitor (Bravo pH Monitoring System) is considered an acceptable alternative to standard catheter-based ambulatory pH monitoring. Medical necessity review for standard catheter based ambulatory pH monitoring does not require medical necessity review.

Background
Gastro-esophageal reflux disease (GERD) is a common condition, with an estimated lifetime prevalence of 25-35% in the US. Patients with GERD often report a compromised quality of life due to symptoms, dietary restrictions, and functional limitations. Complications of GERD include esophagitis, strictures, ulcerations and Barrett’s esophagus. GERD can be diagnosed clinically when patients present with classic symptoms, heartburn and regurgitation. It is more difficult to diagnose in the absence of typical symptoms. Some less typical symptoms such as chest pain and weight loss may indicate GERD or a more serious condition (Scott & Gelhot, 1999).

Diagnostic tests are often used when the diagnosis is unclear or when there is a concern about complications. Possible diagnostic methods are response of symptoms to omeprazole (a proton pump inhibitor), radiology, endoscopy and ambulatory pH monitoring. Radiographic studies may not be useful because only about one-third of patients with GERD have radiologic signs of esophagitis. Endoscopy is more useful for diagnosing Barrett’s esophagus and other complications of GERD than for diagnosing GERD itself.

Ambulatory pH monitoring is currently considered the “gold standard” for diagnosing GERD. It involves placing a nasally passed catheter into the esophagus. The catheter is connected to a monitoring device worn on the patient’s belt and levels of pH are recorded over 24-hours. Many patients find this test uncomfortable. Patients may restrict their daily activities which could result in false negative findings, or may not complete the test due to discomfort (Pandolfino & Kahrilas, 2005; Scott & Gelhot, 1999).

The Bravo pH monitoring system (Medtronic) is a non-invasive alternative to catheter-based ambulatory pH monitoring. This system involves attaching a radiotelemetry pH-sensing capsule (approximately the size of a gel cap) to the mucosal wall of the esophagus. The capsule is placed approximately 6 cm above the
squamocolumnar junction using a customized delivery system that is removed after the capsule is in place. The capsule can be placed orally or trans-nasally, and the procedure is often done during endoscopy.

The capsule measures the pH in the esophagus and transmits the information via radio signal to an external receiver. The pager-sized receiver can be worn on the patient’s belt or waistband. The receiver has a range of 3-5 feet. At the end of the 24-hour or 48-hour testing period, the information from the receiver is uploaded to a computer (Pandolfino, 2005; Medtronic website). Potential advantages of the Bravo system are increased comfort and patient compliance.

The Bravo system had been approved by the FDA and has not been previously reviewed by MTAC.

Medical Technology Assessment Committee (MTAC)

Capsule PH Monitoring System (Bravo System)

08/01/2005: MTAC Review

Evidence Conclusion: Only one study was identified that compared the findings of pH monitoring using the Bravo system and the “gold standard”, catheter-based esophageal monitoring. This study (des Varannes et al., 2005) found that the Bravo system under-reported esophageal acid exposure compared to standard testing. The investigators used a correction factor obtained from their data to determine a cut-off value for abnormal acid exposure as measured by Bravo. After this correction, there was an 88% concordance in diagnostic yield between the two methods. As the authors noted in their conclusion, correction factors have not been standardized. Additional studies are needed to validate an appropriate cut-off value for diagnosing GERD with the Bravo system. The other study that was reviewed (Pandolfino et al, 2003) primarily evaluated the feasibility of using the Bravo system. The investigators were highly successful at placing the Bravo system and recording pH levels. The Pandolfino study included an analysis that compared patient satisfaction with the Bravo and conventional systems. Findings were that the Bravo patients reported more esophageal discomfort and the conventional patients reported more throat discomfort. Overall satisfaction was higher in the Bravo group. Both studies were limited by small sample sizes.

Articles: The search yielded 12 articles, four of which were empirical studies. The ideal study would be an independent, blind comparison of the accuracy of GERD diagnosis using the Bravo PH monitoring system with the “gold standard”, catheter-based esophageal PH monitoring. There was one study that compared these two diagnostic tests (des Varannes et al., 2005) and this was critically appraised. Another study that compared the findings of the Bravo pH monitoring system in healthy patients and patients with a clinical diagnosis of GERD (Pandolfino et al., 2003) was also critically appraised. There were also two case series (n=30 and n=60) that examined the feasibility of using the Bravo pH monitoring system and these were not evaluated further.

The use of capsule PH monitoring system (Bravo System) in the evaluation of gastroesophageal reflux disease (GERD) does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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<th>Date Created</th>
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<td>08/01/2005</td>
<td>Initiated annual review because of Medicare criteria 05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 01/06/2015 MPC, 11/03/2015 MPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 09/02/2014 MPC,</td>
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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Codes

CPT: 91035