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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Capsule pH Monitoring System for Diagnosis of Gastroesophageal Reflux Disease (GERD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	24-Hour Ambulatory Esophageal pH Monitoring (100.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

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 for adults and does not require medical necessity review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastroesophageal 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

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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.

des Varannes SB, Mion F, Ducrotte P et al. Simultaneous recordings of esophageal pH monitoring and a wireless system (Bravo). Gut 2005; Published on-line before journal publication. See Evidence Table. Pandolfino JE, Richter JE, Ours T et al. Ambulatory esophageal pH monitoring using a wireless system. *Am J Gastroenterology* 2003; 98: 740-749. See Evidence Table.

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.*

Applicable Codes

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Medical Necessity Review no longer required:

CPT® Codes	Description
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
08/01/2005	Initiated annual review because of Medicare criteria 05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013MDCRPC, 03/04/2014 MPC, 09/02/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC , 05/02/2023MPC, 03/12/2024MPC	04/23/2020

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
04/23/2020	Added clarification that this criteria policy is applicable to adults.

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