

Corporate Medical Policy

Ingestible pH and Pressure Capsule

File Name: ingestible_ph_and_pressure_capsule
Origination: 11/2009
Last CAP Review: 10/2011
Next CAP Review: 10/2012
Last Review: 10/2011

Description of Procedure or Service

Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal disorders. It can be caused by many conditions; most commonly it is idiopathic, diabetic or postsurgical.

The test considered the reference standard for gastroparesis is called gastric emptying scintigraphy. The patient ingests a radionuclide-labeled standard meal, and then images are performed at 0, 1, 2, and 4 hours postprandially to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

An ingestible capsule (SmartPill® GI Monitoring System) has been cleared for marketing by the U.S. Food and Drug Administration (FDA) via a 510(k) application, with the indication for use to evaluate delayed gastric emptying. Gastric emptying is signaled when the pH monitor in the capsule indicates a change in pH from the acidic environment of the stomach to the alkaline environment of the small intestine. While SmartPill does not measure 50% emptying time, it can be correlated with scintigraphically measured 50% emptying time. The capsule also measures pressure and temperature throughout its transit through the entire gastrointestinal (GI) tract, allowing calculations of total GI transit time. These other functions do not assess delayed gastric emptying, and thus are not evaluated in relation to the approved indication.

*****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

Measurement of gastric emptying using an ingestible pH and pressure capsule is considered investigational for diagnosis of gastroparesis. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

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.

When Ingestible pH and Pressure Capsule is covered

Not applicable.

Ingestible pH and Pressure Capsule

When Ingestible pH and Pressure Capsule is not covered

Measurement of gastric emptying using an ingestible pH and pressure capsule is considered investigational for diagnosis of gastroparesis. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

Overall, the data are scant regarding the diagnostic performance of the SmartPill. Larger studies are needed that compare results with use of this device (using an established protocol and cutoff values) with the current standard test; such studies must define an appropriate gold standard for the diagnosis of gastroparesis. Evaluation of cases with discordant results would be of particular value. Ideally, these studies should be linked to therapeutic decisions and to meaningful clinical outcomes.

The U.S. Food and Drug Administration (FDA) has received one adverse event report according to their Web site, where the capsule was trapped in the stomach of a patient, which required endoscopic removal.

A 2008 consensus statement of the American Neurogastroenterology and Motility Society stated that the impact of wireless pressure and pH capsule on the management of patients with presumed upper GI dysmotility has not been studied.

Since the impact of this technology on net health outcome is unknown, it is considered investigational.

Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: The manufacturer recommends the use of CPT code 91299.

New code effective 1/01/11, 0242T

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

Camilleri M, Bharucha AE, di Lorenzo C et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterol Motil* 2008; 20(12):1269-82.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.81. 8/13/2009

Senior Medical Director - 10/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.81. 1/13/2011

Medical Director review – 10/2011

Policy Implementation/Update Information

11/9/09 New policy adopted. Reviewed with Senior Medical Director 10/9/09. BCBSNC will not provide coverage for ingestible pH and pressure capsule for the measurement of gastric

Ingestible pH and Pressure Capsule

emptying because it is considered investigational. BCBSNC does not cover investigational services. Policy noticed 11/ 9/2009. Effective date 2/16/2010. (btw)

- 6/22/10 Policy Number(s) removed (amw)
- 11/23/10 CPT code 0242T (effective 1/01/11) added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 10/28/10. Policy accepted as written. (adn)
- 11/8/11 Routine annual review. No changes to policy. (adn)

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.