

Corporate Medical Policy

Ingestible pH and Pressure Capsule

File Name: ingestible_ph_and_pressure_capsule
Origination: 11/2009
Last CAP Review: 11/2019
Next CAP Review: 11/2020
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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.

Constipation is a chronic disorder involving infrequent bowel movements, sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation such as mechanical obstruction, metabolic conditions, myopathies, and neuropathies. Diagnostic testing for constipation can aid in distinguishing between two categories of disorders, slow-transit constipation and pelvic floor dysfunction.

Standard tests used in the evaluation of constipation include ingestion of radio-opaque markers and colonic transit scintigraphy. In the radio-opaque markers test, small markers are ingested over one or several days and abdominal x-rays are performed at 4 and/or 7 days. The number of remaining markers correlates with the colonic transit time. In colonic transit scintigraphy, a radio-labeled meal is ingested, followed by scintigraphic imaging at several time intervals. The location of the scintigraphic signals correlates with colonic transit times.

In 2006, an ingestible capsule (SmartPill® GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration (FDA) via a 510(k) process, 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. In 2009, the FDA expanded the use of the SmartPill® to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow versus normal transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill® is not for use in pediatric patients.

The ingestible pH and pressure-sensing capsule (ie, SmartPill GI Monitoring System) measures pH, pressure, and temperature changes to signify passage of the capsule through portions of the GI tract. For example, an increase of 2 or more pH units usually indicates gastric emptying, and a subsequent decrease of 1 or more pH units usually indicates passage to the ileocecal junction. This differs from esophageal pH monitoring for gastroesophageal reflux disease, which measures pH levels in various

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ways, such as through catheters, impedance, or a temporarily implanted device such as the Bravo. The ingestible pH and pressure-sensing capsule (ie, SmartPill) also differs from the wireless capsule endoscopy (ie, PillCam™), which is a capsule swallowed by the patient that transmits video images wirelessly.

Related Policies

Capsule Endoscopy, Wireless
Esophageal pH Monitoring

*****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 gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered investigational for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders. 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.

When Ingestible pH and Pressure Capsule is not covered

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered investigational for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.

Policy Guidelines

Available studies provide some information regarding the comparison of SmartPill ingestible pH and pressure-sensing capsule to other techniques for measuring gastric emptying and colonic transit times, but this evidence primarily consists of concordance with available tests. Since the available tests, such as nuclear scintigraphy, are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies reveal a moderate correlation with alternative tests but provide only limited further information on the true accuracy of the test in clinical care. 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 evidence to date on clinical utility of testing is lacking, consisting of a small number of retrospective studies. This does not provide sufficient information to determine whether health outcomes are improved as a result of the information provided by the SmartPill.

The American and European Neurogastroenterology and Motility Societies issued a position paper on gastrointestinal transit evaluation in 2011. In this position paper, the wireless motility capsule is recommended by consensus for assessing gastric emptying, small bowel, colonic, and whole gut transit times in patients with suspected gastroparesis or gastrointestinal dysmotility in multiple regions.

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However, the position paper notes the clinical utility of identifying delays in small bowel transit times is unknown. 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: 91112

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

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Specialty Matched Consultant Advisory Panel 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.81, 3/14/2013
Specialty Matched Consultant Advisory Panel 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.81, 3/13/2014
Specialty Matched Consultant Advisory Panel 11/2014

Senior Medical Director review 12/2014

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Specialty Matched Consultant Advisory Panel 11/2016

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Specialty Matched Consultant Advisory Panel 11/2018

Medical Director review 11/2018

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Specialty Matched Consultant Advisory Panel 11/2019

Medical Director review 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.81, 11/2019

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 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)
- 10/30/12 Added “In 2009, the FDA expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow versus normal transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill is not for use in pediatric patients” to the Description section. Changed the When Not Covered statement to read “Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered investigational for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders”. Updated the Policy Guidelines. Specialty Matched Consultant Advisory Panel review 10/17/12. (sk)
- 1/1/13 CPT code 0242T removed from policy. CPT code 91112 added to Billing/Coding section. (sk)
- 5/14/13 Reference added. Related policies added. Senior Medical Director review. No change to Policy statement. (sk)
- 1/14/14 Specialty Matched Consultant Advisory Panel review 10/16/13. No change to Policy statement. (sk)
- 5/27/14 Reference added. Senior Medical Director review. Policy guidelines updated. No change to Policy statement. (sk)
- 1/13/15 References updated. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review 12/2014. No change to policy intent. (td)
- 4/28/15 References updated. Description section updated. Billing/Coding section updated to remove code 91299 as there is a specific code. Policy Statement remains unchanged. (td)
- 12/30/15 References updated. Specialty Matched Consultant Advisory Panel review 11/18/2015. Medical Director review 11/2015. (td)
- 1/26/16 References updated. (td)
- 12/30/16 Specialty Matched Consultant Advisory Panel 11/2016. Medical Director review 11/2016. (jd)

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- 12/15/17 References updated. Medical Director review 11/2017. Specialty Matched Consultant Advisory Panel review 11/2017. (jd)
- 12/14/18 References updated. Specialty Matched Consultant Advisory Panel 11/2018. Medical Director review 11/2018. (jd)
- 12/31/19 References updated. Specialty Matched Consultant Advisory Panel 11/2019. Medical Director review 11/2019. (jd)

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.