01-91000-08

Original Effective Date: 01/15/10

Reviewed: 12/05/24

Revised: 12/15/24

Subject: Ingestible pH and Pressure Capsule

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

DESCRIPTION:

An ingestible pH and pressure capsule (e.g., SmartPill GI Monitoring System) is proposed as a means of evaluating gastric emptying, small bowel, colonic and whole gut transit times. This technology is used to evaluate suspected gastrointestinal motility disorders such as gastroparesis, intestinal dysmotility and constipation.

The U.S. Food and Drug Administration (FDA) cleared the SmartPill GI Monitoring System for marketing via a 510(k) application. Indications for used states the SmartPill GI Monitoring System is indicated for use in evaluating patients with suspected delayed gastric emptying (gastroparesis) and for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation.

Summary of Evidence: Thwaites et al (2024) provided an overview of the structure and potential impact of ingestible devices in development that are relevant to the gastrointestinal tract. Technical success of ingestible electronic devices relies on the ability to miniaturize the microelectronic circuits, sensors and components for interventional functions while being sufficiently powered to fulfil the intended function. These devices offer the advantages of being convenient and minimally invasive, with real-time assessment often possible and with minimal interference to normal physiology. Safety has not been a limitation, but defining and controlling device location in the gastrointestinal tract remains challenging. The success of capsule endoscopy has buoyed enthusiasm for the concepts, but few ingestible devices have reached clinical practice to date, partly due to the novelty of the information they provide and also due to the challenges of adding this novel technology to established clinical paradigms. With ongoing technological advancement and as understanding of their potential impact emerges, acceptance of such technology will grow. These devices have the capacity to provide unique insight into gastrointestinal physiology and pathophysiology. Interventional functions, such as sampling of tissue or luminal contents and delivery of therapies, may further enhance their ability to sharpen gastroenterological diagnoses,

monitoring and treatment. The authors noted that while still in relative infancy, the role of ingestible devices in gastroenterology is exciting and provides an opportunity to greatly expand our understanding of gastrointestinal physiology and indeed pathophysiology in a relatively undisturbed and minimally invasive way. It also provides a tool by which changes that may occur in response to pharmacological, dietary or other health interventions over time can be monitored. The authors concluded that the development of miniaturized ingestible microelectronic-based devices offers exciting prospects for enhancing gastroenterological research and the delivery of personalized, point-of-care medicine.

In a review authors Kalantar-Zadeh et al (2017) presented an overview of the gut structure and discusses current and emerging digestible technologies. Ingestible sensing capsules are fast emerging as a critical technology that has the ability to greatly impact health, nutrition, and clinical areas. These ingestible devices are noninvasive and hence are very attractive for customers. With widespread access to smart phones connected to the Internet, the data produced by this technology can be readily seen and reviewed online and accessed by both users and physicians. The outputs provide invaluable information to reveal the state of gut health and disorders as well as the impact of food, medical supplements, and environmental changes on the gastrointestinal tract. One unique feature of such ingestible sensors is that their passage through the gut lumen gives them access to each individual organ of the gastrointestinal tract. Therefore, ingestible sensors offer the ability to gather images and monitor luminal fluid and the contents of each gut segment including electrolytes, enzymes, metabolites, hormones, and the microbial communities. As such, an incredible wealth of knowledge regarding the functionality and state of health of individuals through key gut biomarkers can be obtained. The authors noted that the field of ingestible sensors is still in its absolute infancy and their information about many different sections of the gastro-intestinal tract is still rudimentary. Their “acquisition of knowledge of the gut is so far limited to just a few ingestible sensors including pH, temperature, and pressure capsules as well as camera-based devices. Even such capsules have only been used in relatively low numbers, considering the potential population in need of them. The costs associated with the use and administration of ingestible devices are still high, they have reliability issues, governmental regulatory barriers are still problematic, and lack of familiarity of medical doctors and food scientists with the output information from capsule signals is also a significant issue.”

In a review Lacy et al (2022) outlines a strategy for defining, diagnosing, and managing medically refractory gastroparesis. The review was commissioned and approved by the American Gastroenterological Association (AGA) Institute Clinical Practice Updates Committee and the AGA Governing Board. The best practice statement includes the following for gastric emptying: “Clinicians should verify appropriate methodology of the gastric emptying study to ensure an accurate diagnosis of delayed gastric emptying.” “Because the wireless motility capsule, an inanimate object, identifies the phase III activity front of the migrating motor complex rather than overall gastric emptying, a meal-based test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the wireless motility capsule.

POSITION STATEMENT:

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule (e.g., SmartPill Monitoring System) is considered **experimental or investigational** for all indications, including the evaluation of gastroparesis, constipation and gastrointestinal motility disorders. The evidence is insufficient to determine the effects

of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (**investigational**)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Gastroparesis: delayed gastric emptying.

RELATED GUIDELINES:

Esophageal pH Monitoring, 01-91000-01

Wireless Capsule Endoscopy, 01-91000-35

OTHER:

Other names use to describe SmartPill GI Monitoring System:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Gastrointestinal motility system
Gastrointestinal pH and pressure monitoring equipment
SmartPill
Wireless GI motility monitoring
Wireless motility capsule

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/5/24.

GUIDELINE UPDATE INFORMATION:

01/15/10	New Medical Coverage Guideline.
12/15/10	Annual review. Maintain position statement. Updated references.
01/01/11	Annual HCPCS coding update; added 0242T.
02/15/12	Annual review. Maintain position statement (experimental or investigational); revised to include constipation and other gastrointestinal motility disorders and added statement "the impact of measuring gastric emptying using an ingestible pH and pressure capsule on health outcome is unknown." Updated description and references.
01/01/13	Annual HCPCS coding update; deleted 0242T and added 91112.
03/15/13	Annual review; no change in position statement. Updated references.
06/15/14	Annual review; no change in position statement. Added Medicare Advantage products program exception Updated references.

05/15/17	Review; no change in position statement. Updated references.
12/15/19	Review; no change in position statement. Updated references.
12/15/21	Review; no change in position statement. Updated references.
05/22/23	Update to Program Exceptions section.
12/15/23	Review; revised position statement. Updated references.
12/15/24	Review; no change in position statement. Updated references.