Coverage Guidelines

SmartPill® gastrointestinal (GI) wireless motility capsule (WMC)

Disclaimer:
Please note that Baptist Health Plan Coverage Guidelines may be updated throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

DEFINITION

The SmartPill® gastrointestinal (GI) wireless motility capsule (WMC) was created to evaluate suspected gastric and intestinal motility disorders including gastroparesis, dyspepsia, and chronic constipation. WMC is a self-contained electronic device that is ingested naturally into the digestive tract. As WMC passes naturally through the body after being swallowed, data including luminal pH, temperature, pressure, and gastric emptying time are recorded and transmitted wirelessly to a receiver worn by the patient during the evaluation period.

The WMC is generally eliminated 24 to 48 following consumption through the stool and the receiver is submitted for data review. Follow up imaging studies can be used to verify that WMC has been passed naturally through the digestive tract. WMC is performed in an outpatient setting.\(^1\), \(^2\)

COVERAGE CRITERIA

The SmartPill® gastrointestinal (GI) wireless motility capsule (WMC) is not currently considered medically necessary or is considered experimental / investigational due to a lack of quality randomized, controlled clinical trials that demonstrate efficacy as compared to conventional diagnostic methods.

MEDICAL BACKGROUND

Gastric motility disorders describe the failure of the stomach to contract and empty as part of a coordinated process involving the electrical and physical activity of key muscle groups. The most common result of this breakdown is referred to as gastroparesis characterized by delayed gastric emptying without evidence of obstruction. Clinical symptoms of gastroparesis include...
early or easy satiety, bloating, chronic nausea, frequent vomiting, chronic constipation and weight loss. Gastroparesis is commonly associated with diabetes mellitus in which the disorder evolves from hypoglycemia or gastric neuropathy. Gastroparesis is also diagnosed in patients without diabetes mellitus where the cause of the disorder can be idiopathic. Complications of gastroparesis may include hypoglycemia, hyperglycemia, electrolyte imbalance, malnutrition, exacerbation of diabetes associated complications, and frequent hospitalizations. Gastric motility disorders can also affect the intestines, with symptoms including nausea, vomiting, and chronic constipation sometimes resulting in a misdiagnosis of irritable bowel syndrome.\(^3\)\(^4\)

Gastric motility disorders are diagnosed using invasive techniques and involve imaging studies and exposure to radiation or radioactive materials. These diagnostic methods may include electrogastrography of the stomach, electromyography of the anal sphincter, gastric or colonic transit time measurement with radioactive or radiopaque markers, anorectal manometry, assessment of stool form and frequency, and defecography of a radiopaque paste.\(^5\)\(^6\)\(^7\)\(^8\)

The SmartPill® gastrointestinal (GI) wireless motility capsule (WMC) was developed as a noninvasive alternative to conventional diagnostic techniques involving the use of a small capsule that is ingested and naturally passes through the digestive tract. The self-contained electronic device measuring 13 x 26 mm records and wirelessly transmits acid levels, temperature, and pressure of the digestive tract to a wearable device that is submitted for data analysis following the examination.\(^9\)\(^10\) Although the advantages of WMC include the noninvasive testing approach as well as a lack of exposure to radiation or radioactive materials, the efficacy of WMC as compared to conventional proven diagnostic methods has not been established.

A review of the peer-reviewed medical literature identified limited evidence to define the clinical utility of WMC. A 2015 retrospective chart review of 161 patients tested using WMC found that 109 abnormal test results led to the diagnosis of a gastric motility disorder including 17 (15.6%) with delayed gastric emptying, 13 (11.9%) with delayed small bowel transit, 25 (22.9%) with delayed large bowel transit, and 54 (49.5%) with multiregional dysmotility. However, this test did not measure the efficacy of WMC as compared to another diagnostic method and it did not demonstrate an impact on patient management or clinical outcomes.\(^11\)

In a 2014 review, Hasler and colleagues noted that despite potential benefits of WMC, its recommended use has been undermined by limited data with small sample sizes and important study-design limitations.\(^12\) In a 2012 updated report from Hayes Medical Technology Directory, WMC was assigned a D rating given that evidence did not demonstrate a diagnostic accuracy that was comparable to conventional diagnostic tests. For example, SmartPill was not as accurate as radiopaque markers in diagnosing delayed colonic transit in patients with chronic constipation. The Hayes report noted that additional studies were needed to determine whether use of the WMC improves the diagnosis and treatment of gastrointestinal motility disorders.

Additionally, current published guidelines did not recommend the use of WMC given the current limited availability of evidence. In the most recent publication of clinical practice guidelines from the American College of Gastroenterology, WMC was addressed and described, but the report does not define the test as an alternative pending further validation.\(^13\) The Federal Agency for Healthcare Research and Quality (AHRQ) addressed WMC in their most recent 2013 report noting that WMC appears to be efficacious with a sensitivity between 59% and 86% and a specificity between 64% and 81%, but existing data was insufficient to determine whether use of WMC will improve outcomes of care.\(^14\) In a 2017 guideline published by UpToDate, WMC was described as an alternative to conventional diagnostic tests with notable advantages, but the guidelines stress that further studies are needed before this modality can be recommended.\(^15\)
REGULATORY INFORMATION

No legislative mandates were found for coverage of the SmartPill® gastrointestinal (GI) wireless motility capsule (WMC) devices in either Kentucky or Indiana.¹⁶

Baptist Health Plan Coverage Guidelines are created to provide members and providers with peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

COVERAGE DETAIL

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>91112</td>
<td>Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10® Procedure Codes</th>
<th>Description</th>
<th>Coverage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>4A0B78Z</td>
<td>Measurement of Gastrointestinal Motility, Via Natural or Artificial Opening</td>
<td>Is not currently considered medically necessary or is</td>
</tr>
<tr>
<td>ICD-10® Diagnosis Codes</td>
<td>Description</td>
<td>Coverage Information</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>K20.0-K31.9</td>
<td>Diseases of esophagus, stomach and duodenum</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational for SmartPill®</td>
</tr>
<tr>
<td>K55.011-K64.9</td>
<td>Diseases of intestines</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational for SmartPill®</td>
</tr>
<tr>
<td>Q43.1-Q43.2</td>
<td>Hirschsprung’s disease and other congenital functional disorders of the colon</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational for SmartPill®</td>
</tr>
<tr>
<td>R10.0-R19.8</td>
<td>Symptoms involving digestive system and abdomen</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational for SmartPill®</td>
</tr>
</tbody>
</table>

**REFERENCES**

2. Hayes, Inc. Hayes Medical Technology Directory. *SmartPill® GI monitoring system (SmartPill*
Delayed gastric emptying
Gastric motility disorders
Gastroparesis
Multiregional dysmotility
Radiopaque markers
Scintigraphy
SmartPill®
Wireless motility capsule (WMC)