**Medica Coverage Policy**

<table>
<thead>
<tr>
<th>Policy Name:</th>
<th>Gastrointestinal Monitoring System (SmartPill®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>10/16/2017</td>
</tr>
</tbody>
</table>

**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**
Gastrointestinal Monitoring System (SmartPill) is investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** See the following related Medica coverage policy: Wireless Capsule Endoscopy and/or Wireless Esophageal pH Monitoring (Bravo™ System).

**Description**
Gastroparesis is a common chronic disorder, characterized by delayed gastric emptying without evidence of mechanical obstruction. Its most common symptoms include constipation, nausea, vomiting, early satiety, bloating, abdominal pain, and post-prandial fullness. The cause of gastroparesis is often unknown, but may include diabetes, medication, Parkinson’s disease, or multiple sclerosis. Gastric emptying scintigraphy (GES) is a standard method of assessing gastric motility in gastroparesis.

The SmartPill was approved in 2006 and is intended for the evaluation of patients with suspected delayed gastric emptying. It is an ingestible, wireless device about the size of a large vitamin, equipped with sensors. As it passes through the gastrointestinal tract, the miniaturized sensor technology measures pressure, temperature and pH, as well as real and elapsed time. Acquired data are continuously transmitted over very low power radiofrequencies to a small receiver that can be worn on the patient’s belt. After the study has been completed (the duration of which may depend on anatomic area of interest), the patient returns the receiver to the physician, who can then download and view the data on a computer. The disposable device is expelled naturally and does not need to be retrieved.

**FDA Approval**
SmartPill GI Monitoring System® received U.S. Food and Drug Administration (FDA) 510(k) clearance (K053547) on July 18, 2006, and version 2.0 was cleared on October 30, 2009, under the same process. The SmartPill is manufactured by The SmartPill Corporation (Buffalo, NY, USA). This device was cleared for marketing by the FDA for the evaluation of patients with suspected delayed gastric emptying.
**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes:**
- 91112: Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report.

Original Effective Date: 2/1/2009

Re-Review Date(s): 7/26/2011
8/20/2014
8/16/2017
2/10/2020 – administrative update; format