I. Policy: Wireless Capsule Endoscopy

II. Purpose/Objective:
To provide a policy of coverage regarding Wireless Capsule Endoscopy

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**DESCRIPTION:** Capsule endoscopy is performed using an imaging system consisting of a swallowable disposable capsule containing a video camera, light source, radiotransmitter and batteries; an externally worn data recorder and an office based workstation. Up to 50,000 images are recorded and transmitted to the data recorder as the capsule camera travels through the gastrointestinal tract, propelled by peristalsis. The capsule is excreted approximately 8-72 hours after ingestion and is discarded.

**SmartPill® GI Monitoring System** is an ingestible capsule which is thought to sense and record pH and pressure measurements from the entire length of the gastrointestinal tract in order to evaluate patients with suspected delayed gastric emptying. These measurements are used to then determine gastric emptying time (GET), total transit time (TTT), and combined small-large bowel transit time (SLBTT). In addition the pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

**INDICATIONS:** Wireless capsule endoscopy may be considered medically necessary, as a diagnostic imaging tool, in the following clinical circumstances:

- **Occult Gastrointestinal Bleeding**
  Limited to members who have undergone upper gastrointestinal (GI) endoscopy, colonoscopy and small bowel imaging studies and these tests have failed to reveal a source of bleeding. The bleeding must be of a nature that there is documentation of anemia secondary to the loss of blood.

- **Small Bowel Neoplasm**
  Limited to the detection of neoplasms of the small bowel in members who are symptomatic for a neoplasm (e.g., GI bleeding, partial bowel obstruction) and when the diagnosis has not been confirmed by upper GI endoscopy, colonoscopy, push enteroscopy, and nuclear imaging or radiologic procedures.

- **Crohn’s Disease**
  Limited to members who are symptomatic for Crohn’s disease (e.g., diarrhea, GI bleeding, abdominal pain) and who have undergone complete lower GI studies (e.g. Colonoscopy or barium enema), and an upper GI with small bowel follow-through and the testing has failed to reveal the source of the symptoms.

**For Medicaid lines of Business:**
Evaluation of Celiac Disease for individuals with a negative biopsy and when the diagnosis has not been confirmed by upper GI endoscopy, push enteroscopy, colonoscopy, nuclear imaging or radiological procedures.

**LIMITATIONS:**
- The device must be FDA approved
- Capsule endoscopy is contraindicated in persons with known or suspected gastrointestinal obstruction, strictures, or fistulae

**EXCLUSIONS:**
Wireless capsule endoscopy is not intended for use as a gastrointestinal cancer-screening tool. This use is considered Not Medically Necessary and is NOT COVERED.

Wireless capsule endoscopy is Not Medically Necessary and NOT COVERED for the confirmation of lesions or pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum)

The Plan does NOT provide coverage for the use of a wireless capsule for measuring gastric emptying (**SmartPill® GI Monitoring System**) for all indications including but not limited to gastroparesis because it is considered experimental, investigational or unproven. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes when compared to established technologies.

The Plan does NOT provide coverage for the use of the Agile patency capsule because it is considered experimental, investigational or unproven for evaluating patency of the gastrointestinal tract before wireless capsule endoscopy, and for all other indications. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes.
Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Wireless Capsule Endoscopy
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.

HCPCS/CPT Codes

91110    Gastrointestinal tract imaging, intraluminal (eg., capsule endoscopy), esophagus through ileum, with physician interpretation and report
91111    Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with physician interpretation and report
91112    Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
0355T    Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


This policy will be revised as necessary and reviewed no less than annually.


ECRI Institute. HTAIS Custom Hotline Response (online). SmartPill GI Monitoring System for Assessing Gastric Motility. ECRI Institute. Current as of 02/02/07.


ECRI Institute. HTAIS Hotline. Capsule endoscopy for the diagnosis of obscure small bowel bleeding. 10/14/10


This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/03
Revised: 5/04; 5/07; 5/09(wording), 5/10 (ref), 4/11 (exclusion, refs)