

Request to Reassign Wireless Motility Capsule to APC 0142

Advisory Panel on Hospital Outpatient Payment

March 11-12, 2013



Expanding the Scope of GI

SmartPill Wireless Motility Capsule (WMC)

FDA Indications for Use (510k)

The WMC measures pressure, pH, temperature and transit times throughout the GI tract for use in evaluating patients with suspected delayed gastric emptying (Gastroparesis) and chronic constipation.

These measurements are used to:

- Characterize pH profiles in the GI tract
- Determine gastric emptying time
- Determine small bowel transit time
- Determine colonic transit time
- Determine whole gut transit time
- Characterize pressure patterns and provide motility indices for the antrum and duodenum



Population Symptoms Profile and WMC Benefits

Symptoms Profile:

- Patients Presenting with Nausea, Vomiting, Early Satiety, Bloating, Abdominal Discomfort (Pain) and Constipation
 - Overlap of upper and lower GI symptoms
 - Negative endoscopy, colonoscopy and/or imaging studies
 - Refractory to pharmacologic therapy

Benefits:

- Evaluates GI tract motility from stomach to colon
- Standardized test protocol with inter-rater reliability
- Eliminates need for repeated radiological, scintigraphic, and segmental motility testing
- No radiation exposure
- Reduces clinical service line and diagnostic cycle time

Diagnostic Utility of WMC in Gastrointestinal Dysmotility (86 patients)¹

- WMC yield 50% more relevant pathophysiologic information than conventional tests (GES and ROM)
 - 50% diagnostic gain
- Therapeutic intervention influenced by WMC
 - Upper GI 50%
 - Lower GI 30%
- Observed SBTT delay 15%

¹Rao S.S.C., Valestin J. Diagnostic Utility of Wireless Motility Capsule in Gastrointestinal Dysmotility. *Journal of Clinical Gastroenterology* 2011; 45 (8): 684-690.

Patient Clinical Vignette¹

- Female with infrequent BM, generalized pain, nausea/vomiting
 - Refractory to fiber, bisacodyl and lubiprostone
 - Colonoscopy revealed inadequate bowel prep
- WMC Results:
 - Normal stomach & SB: Severe delayed colon (WGTT>127hrs)
 - Eliminated need for GES, SBFT and 7 day ROM test
 - WMC Results: Absence of upper GI delay helped determined suitability for elective colectomy

¹Saad R., Hasler WL. A Technical Review and Clinical Assessment of the Wireless Motility Capsule. *Gastro & Hep* 2011; 7 (12): 795-804.

WMC Economics in a Hospital Setting

- Current CPT code value for 91112 is \$1,188.93.
- WMC Equipment
 - Hardware & software Capital \$20,000.00
 - WMC capsules Disposable \$600.00
- Hospital Overhead
 - Facility costs including staff \$800.00
- The limited reimbursement valuation currently proposed will restrict availability of the WMC test in the Medicare eligible population at hospital outpatient institutions even when medically necessary.
- CMS based their decision on a limited number of claims due to the low APC payment value which deterred availability of the WMC Procedure for Medicare patients.

Proposal: Reassign WMC to APC 0142

- **APC 0361**
 - 2013 Proposed Payment - **\$302.60**
 - Other procedures in APC are dissimilar to WMC based on:
 - Type of test: Fixed catheter and/or single GI region tests
 - Resource/cost structure
 - WMC measures multiple regions of GI tract, captures data during transit and uses pH data as anatomical locator vs direct measure of dysfunction
- **APC 0142**
 - 2013 Proposed Payment - **\$750.68**
 - Clinical coherence: Capsule based diagnostic test of alimentary tract
 - Resource coherence: Hospital based GI/Nurse resources utilized to conduct test