COVERAGE:

Wireless Capsule Endoscopy (WCE) is considered **medically necessary** to:

- identify the source of obscure small bowel bleeding, which has been undetected by standard diagnostic methods (such as colonoscopy and/or upper gastric endoscopy) WITH significant unexplained anemia (hemoglobin of equal to or less than 10 gm) due to overt bleeding (non-reproductive system related) and associated with occult bloody stool; or,
- identify the source of other gastrointestinal pathology as in a small bowel tumor.

Wireless Capsule Endoscopy (WCE) is considered **experimental or investigational** to:

- identify the source of esophageal, gastrointestinal or colonic bleeding, or
- be utilized as a gastrointestinal screening examination for asymptomatic patients.

DESCRIPTION:

Wireless Capsule Endoscopy (WCE) is performed using the M2A Given Diagnostic Imaging System, which is a disposable imaging capsule. The capsule measures 11 by 30 millimeters and contains video imaging, self-illumination, and image transmission modules as well as a battery supply that lasts for up to eight hours. The indwelling camera takes images at a rate of two frames per second as the wave like movement of the intestine carries the capsule through the gastrointestinal tract. The average transit time from ingestion to evacuation is 24 hours. The WCE device uses wireless radio transmission to send the images to a receiving recorder device that the patient wears around the waist. The receiving device also contains some localizing antennae sensors that can roughly gauge when the image was taken over the abdomen. Images are downloaded onto a workstation for viewing and processing.

Obscure bleeding refers to intermittent or chronic bleeding of unknown origin with negative endoscopy, colonoscopy, and/or small bowel series results. Obscure bleeding can be subcategorized into either (1) obscure-occult (recurrent iron-deficiency anemia and/or recurrent positive fecal occult blood test results) or (2) obscure-overt (recurrent passage of visible fecal blood).

WCE **MAY BE** known by several different names, such as:

- Camera Pill,
- Pill-Size Swallowable Camera,
- Rapid Capsule Endoscopy,
• Given M2A, and
• Edible Camera.

RATIONALE:

The estimated annual incidence of gastrointestinal bleeding in the United States is approximately 100 episodes per 100,000 persons, resulting in 300,000 hospitalizations annually. Diagnostic tools such as radiologic studies and endoscopic examination often fail to identify a source of bleeding, resulting in a cycle of repetitive testing over months or even years.

Review of literature on current diagnostic tools for obscure bleeding of the small intestine and examination of data from the first U.S. clinical trial suggest that this new technology potentially has significant clinical, economic, and humanistic benefits. Of the 21 patients enrolled in the trial, one patient was excluded due to a technical malfunction. The mean age was 61 years. The mean length of time since first recognition of bleeding was 2.7 years. The patients in this study averaged more than 10 procedures without any diagnostic finding prior to WCE. A bleeding site was located via WCE in 12 of the 20 patients (60% yield), and push enteroscopy found the cause in 7 of the 20 (35% yield). The negative diagnostic result in the 8 remaining patients suggests that the cause of bleeding is not within the small intestine. The push enteroscopy provided a negative result in 13 of the 20 patients, but the result is not as meaningful since only one third of the 22 foot intestine could not be viewed.

The American Gastroenterological Association literature review and recommendations on the evaluation and management of occult and obscure gastrointestinal bleeding (published January 2000) states, "The original work-up of most cases of occult bleeding should not require diagnostic testing other than colonoscopy and/or upper endoscopy, even when the results of these procedures are negative. Further diagnostic evaluation is necessary only when there are extenuating clinical circumstances or evidence of persistent or recurrent bleeding, which by definition becomes obscure bleeding."

The WCE device was approved by the FDA in August 2001 to be used "along with - not a replacement for - other endoscopic and radiological evaluations of the small bowel." The FDA further clarified that the "capsule was not studied in the large intestine."

PRICING:

None

REFERENCES:
WIRELESS CAPSULE ENDOSCOPY (WCE)
RAD601.042
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003


DISCLAIMER:
State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.
HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.