Medical Coverage Policy | Magnetic Capsule Endoscopy

EFFECTIVE DATE: 06|01|2022
POLICY LAST UPDATED: 02|02|2022

OVERVIEW

The magnetic capsule endoscopy (CE) uses a noninvasive device to visualize segments of the gastrointestinal (GI) tract. Patients swallow a capsule that records images of the intestinal mucosa as it passes through the GI tract. The capsule is collected after being excreted and images interpreted. There are two types of capsules, wireless and magnetic.

This policy is for the magnetic capsule only.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Magnetic capsule endoscopy is not covered for the evaluation of patients with unexplained upper abdominal complaints and all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

Commercial Products

Magnetic capsule endoscopy is considered not medically necessary for the evaluation of patients with unexplained upper abdominal complaints and all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

BACKGROUND

Magnetic Capsule Endoscopy for Patients with Suspected Gastrointestinal Disorders

For individuals who have unexplained upper abdominal complaints who receive magnetic CE, the evidence includes diagnostic accuracy studies. Relevant outcomes are test validity, symptoms, change in disease status, and treatment-related morbidity. Studies evaluating the diagnostic characteristics of magnetic CE as compared to conventional gastroscopy in the target population have generally demonstrated similar accuracy, sensitivity, and specificity, with increases in patient preference and an acceptable safety profile with the magnetic CE approach. However, the diagnostic characteristics of magnetic CE are inadequate to substitute for other modalities or to triage patients to other modalities based on the current literature. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Magnetic Capsule Endoscopy

The U.S. Food and Drug Administration (FDA) approved a novel magnetically maneuvered CE system (NaviCam™; AnX Robotica, Inc.) in May 2020. This system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images

of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The system is non-invasive, does not require sedation, and has a procedural time of approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as 2 weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those <22 years of age, and those with a body mass index ≥38.

CODING

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0651T Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report (Effective 7/01/2021)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, March 2022

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