

EFFECTIVE DATE: 06|01|2022

POLICY LAST REVIEWED: 03|04|2026

OVERVIEW

The magnetic capsule endoscopy (MCE) uses a noninvasive device to visualize segments of the gastrointestinal (GI) tract. Individuals 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.

Note: This policy addresses magnetic capsule endoscopy only and does not address wireless capsule endoscopy.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Magnetic capsule endoscopy is not covered for the evaluation of individuals 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 individuals 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

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 less than 22 years of age, and those with a body mass index of 38 or greater. Other magnetically controlled devices have since received approval, and the NaviCam Small Bowel Capsule is now AI-assisted.

Regulatory Status

Wireless Capsule Endoscopy Devices Cleared by the U.S. Food and Drug Administration:

- NaviCam Small Bowel Capsule Endoscopy System (Manufacturer: Ankon Technologies Co., Ltd.)
- NaviCam Capsule Endoscope System with NaviCam Stomach Capsule (Manufacturer: AnX Robotica, Inc.)
- NaviCam Stomach Capsule System (Manufacturer: AnX Robotica, Inc.)
- NaviCam Xpress Stomach System (Manufacturer: AnX Robotica, Inc.)
- NaviCam Xpress Stomach Capsule Endoscope System (Manufacturer: AnX Robotica, Inc.)

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 sequence and chronology of testing and treatment recommended before magnetic CE needs to be defined to determine whether magnetic CE has utility to diagnose the condition. No RCTs assessing the clinical utility of magnetic CE for this indication were identified.

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.

CODING

Medicare Advantage Plans and Commercial Products

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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, May 2026

Provider Update, March 2025

Provider Update, March 2024

Provider Update, March 2023

Provider Update, March 2022

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