ANX ROBOTICA


***Converging Robotics & AI...a new vision of GI diagnostic & therapeutic excellence***

# Procedural Reimbursement Guide

## 2024

## Our History

Headquartered in Plano, Texas, AnX Robotica brings versatility in development and integration of technologies including precise magnetic control, in house ASIC design, artificial intelligence, micro-optical imaging, image processing, and wireless transmission to improve care for patients. With more than 200 patents granted or applications pending, and dozens of clinical papers published in major international journals, AnX Robotica, together with its sister companies, have become a leading robotic capsule technology company.

Our company's roots go back to 2008, when our founders began designing and building the basic Robotic Capsule Endoscopy technology in Silicon Valley. With the vision to develop and manufacture advanced medical devices for diagnosing and treating digestive diseases, they established ANKON Medical Technologies in 2009, which was the first company in the world to commercialize a "Magnetically Controlled Capsule Endoscopy System." In 2019, U.S. based AnX Robotica established a commercial agreement to share products and technologies with ANKON.

In May of 2020, FDA granted AnX Robotica the De Novo request for the NaviCam® Stomach System, the world's first commercialized magnetically controlled robotic platform for stomach visualization. The NaviCam® Stomach System utilizes advanced robotic technologies combined with innovative and intelligent software to give medical practitioners external robotic control of capsules inside the human body.

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The provider has the responsibility to determine medical necessity and to submit appropriate codes, documentation and charges for care provided. AnX Robotica makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service.

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## Understanding the NaviCam® Stomach System– Magnetically Controlled Capsule Endoscopy (MCCE) System

The NaviCam® Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥6 years old with a BMI ≤65 and a waist circumference ≤77 inches. The system can be used in clinics and hospitals, including ER settings. The NaviCam® Stomach System is a capsule endoscopy system designed to obtain images of the stomach. It differs from other capsule endoscopy systems, such as those used for small bowel examination, as the NaviCam® Stomach System utilizes magnetic fields to allow the physician to navigate the capsule within the gastric anatomy.

The NaviCam® Stomach System consists of an ingestible capsule and external magnetic controller used for visualization of the stomach. The capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is located outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction. The stomach capsule endoscopy system utilizes precise, multi-dimensional rotation and movement of a robotic arm with adaptive matching to achieve precise control of the capsule for a complete and accurate examination of the stomach.

NaviCam® Stomach System has five main components:

1: Ingestible Capsule

2: Data Recorder

3: Controller

4: Capsule Locator

5: ESview Software

## Clinical Utility of MCCE

MCCE is an alternative diagnostic imaging tool which is used to visualize the stomach without the use of anesthesia.

Medically Necessary services are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a covered individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the covered individual's illness, injury or disease; and
- not primarily for the convenience of the covered individual, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that covered individual's illness, injury or disease.

### What makes MCCE different

- MCCE does not require sedation.
- There is virtually no risk of perforation with MCCE.[1]
- MCCE can view the stomach in its natural state rather than the sedated invasive state, which may be important for the diagnosis of motility and other functional conditions.
- MCCE can navigate a 180° turn in order to view the esophageal sphincter in its natural state.
- The physician may be able to visualize and speak with the patient in real time rather than wait for the patient to return the next day and longer for the reading to be completed.
- Use of MCCE may lead to improved patient satisfaction due to: a) faster diagnosis, b) fewer visits to the clinic/hospital, c) assurance that a thorough visualization is completed.
- In MCCE, the patient can eat and drink as soon as the procedure is over.

1. In the CFDA clinical study, no adverse events were reported. In the Comparative Study, among the 350 patients included in the study, adverse events reported did not include perforation.

# SECTION 3: COVERAGE

Covered benefits under commercial health plans can vary by health plan and by the individual or group purchasing health plan coverage. It is important that you verify the specific benefits by group and plan of the patient being considered for the procedure.

***Medical Necessity and Prior Authorization***

Medical necessity may need to be established prior to any service or procedure being considered for coverage or payment. Individual payers develop their own criteria for medical necessity. Payers and Medicare Advantage plans should be consulted for their medical necessity guidelines.

Prior authorization is a process initiated by the ordering physician in which the payer verifies the medical necessity of a treatment in advance using independent objective medical criteria. It is the ordering/prescribing provider's responsibility to determine which specific codes require prior authorization. Prior authorization is subject to covered benefit review and is not a guarantee of payment.

A letter of medical necessity may be required. Such letter, addressed to the payer Medical Director, should include:

- Patient information – name, date of birth, policy number
- Details of the patient's medical history
  - Current diagnosis(es)
  - Duration and degree of illness or injury
  - Summary of past treatment(s) (i.e. conservative care or other interventions)
  - Current status (why previous treatments failed)
  - Reason for proposed treatment
- Description of the patient's current status and treatment plan
  - Ability to work
  - Activities of daily living
- Proposed procedure(s) and rationale for treatment
- Proposed location of service and dates planned
- Billing codes

***Sample Preauthorization Request/Letter of Medical Necessity***

Re: Preauthorization Request for Service

Patient's Name:

Date of Birth:

Subscriber/Policy #:

Group #:

To Whom This May Concern:

This letter is to request approval for the procedure needed for (patient's name) who suffers from (diagnosis). (Patient's name) has suffered from (list all symptoms) since (date), despite efforts to manage (his/her) symptoms using (previous treatments).

(Specific symptoms) are impacting (patient's name) lifestyle, job, family and wellbeing. (Patient's name) symptoms have steadily progressed, and conservative treatment options have failed to alleviate the symptoms. Based on the patient's presentation and physical findings, I am recommending a magnetically controlled capsule endoscopy (MCCE) procedure.

This MCCE procedure utilizes precise, multi-dimensional rotation and navigation of the imaging capsule to achieve a complete and accurate examination of the patient's stomach. The procedure requires no anesthesia. I prefer to perform this procedure at (name of facility).

Please advise me immediately if benefits are available for this procedure and/or if additional information is required. Because (patient's name) is in considerable discomfort and (his/her) condition is impacting (his/her) quality of life, we appreciate your immediate attention to this request.

Sincerely,

Physician Name

***Patient Selection Criteria/Indications***

Appropriate patient selection is critical to coverage and payment for any procedure or service.

The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥6 years old with a BMI ≤65 and a waist circumference ≤77 inches. The system can be used in clinics and hospitals, including ER settings.

***Contraindications***

NaviCam Stomach Capsule is contraindicated in the following circumstances:

- Patients with known or suspected gastrointestinal obstruction, stenosis or fistula.
- Patients implanted with electronic or electronically conductive implants of metals, especially those containing ferromagnetic foreign matter.
- Patients with dysphagia with risk of aspiration.
- Pregnant women.

***Preauthorization Process***

Preauthorization is a process that allows physicians and other health care providers to determine, prior to treating the patient:

- If the patient is a covered member
- If the treatment is covered
- If the site of service for the treatment is covered
- The amount of co-payments/co-insurance, deductibles, and the patient's maximum benefits

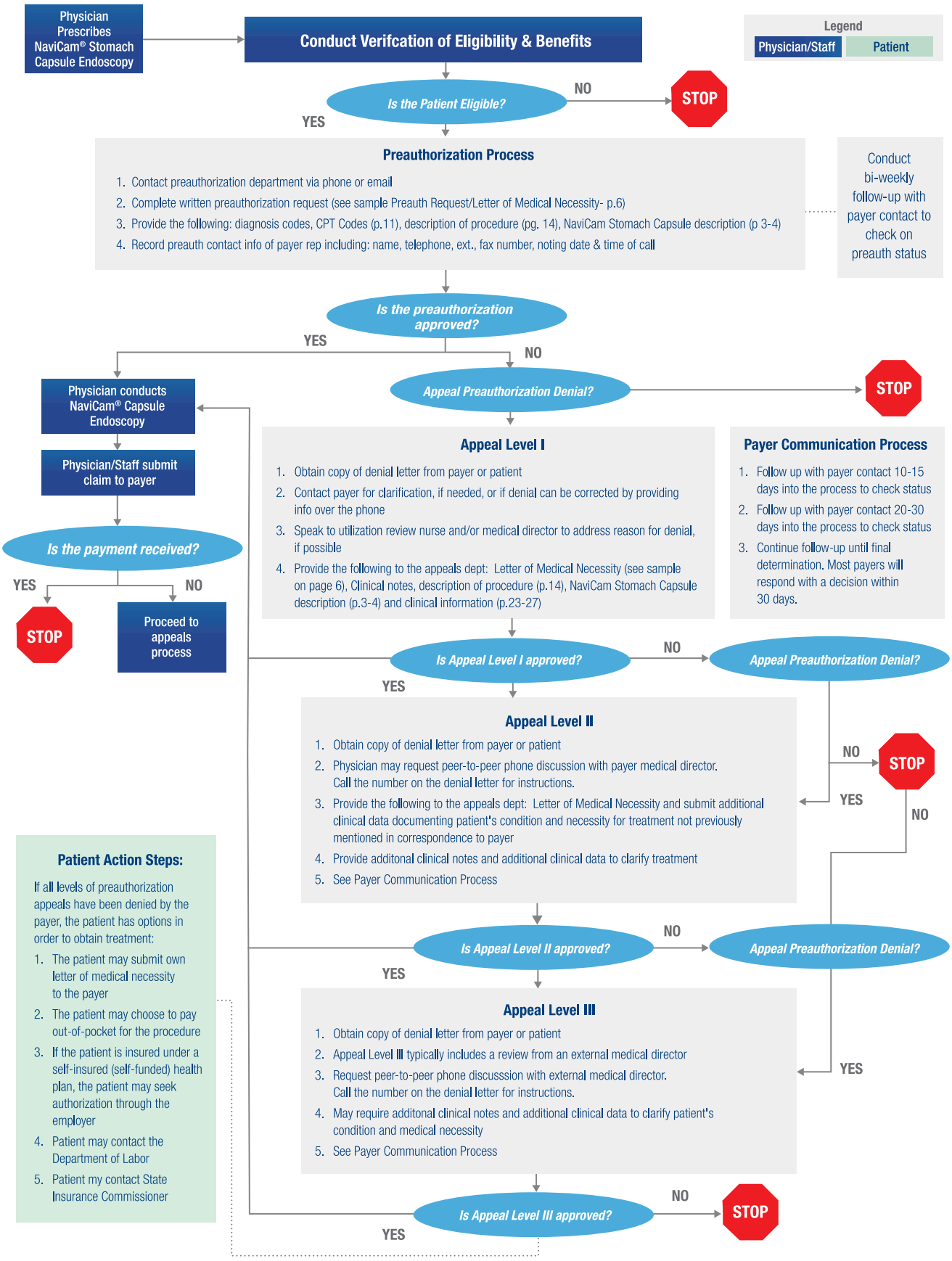
Preauthorization clarifies benefits in advance, allowing the physician and patient to make informed decisions regarding treatment.

We strongly recommend consulting the payer with respect to coverage policies and benefits specific to each patient's coverage. Many commercial payers require procedures be preauthorized. Original fee-for-service Medicare does not preauthorize services.

A preauthorization is not a guarantee of payment. Final determination will be subject to valid eligibility, applicable benefits, and medical necessity at the time of rendered services. Instead, services are reviewed for medical necessity and coverage conditions when the claim is received. Accordingly, prior to treatment, we strongly recommend your patient sign a Waiver of Financial Liability (Non-Medicare), in the event of a non-coverage or partial coverage decision.

Once a patient has been identified, medical necessity established, selection criteria met, and a Waiver of Financial Liability signed by the patient, a preauthorization request should be submitted to the patient's in insurance carrier. The following steps should assist in the preauthorization process:

- A call should be placed to the payer to verify insurance benefits and to determine if preauthorization is required
- Prepare letter of preauthorization request/medical necessity or certificate of medical necessity
- Submit the letter and documentation to the Medical Director including:
  - Copies of peer reviewed published studies supporting your treatment plan
  - NaviCam® Stomach System product information
  - FDA clearance letter
  - Copy of patient's insurance card
  - Physician notes regarding patient's history and current medical condition
  - Copies of previous medical records
  - Results of imaging and other diagnostic tests
- If you have not received a response within 30 days, follow up with the health plan by phone
- Records should be sent by fax, by standard mail or express mail, with return receipt requested, or by secure electronic transmission to the payer (if available)
- Document all contact with the insurer, including the name, department, and contact phone number of the person with whom you communicated
- Do not send protected health information through non-secure/non-encrypted e-mail


Physician Prescribes NaviCam® Stomach Capsule Endoscopy
Conduct Verifcation of Eligibility & Benefits
Legend
Physician/Staff
Patient
Is the Patient Eligible?
NO
STOP
YES
Preauthorization Process
1. Contact preauthorization department via phone or email
2. Complete written preauthorization request (see sample Preauth Request/Letter of Medical Necessity- p.6)
3. Provide the following: diagnosis codes, CPT Codes (p.11), description of procedure (pg. 14), NaviCam Stomach Capsule description (p 3-4)
4. Record preauth contact info of payer rep including: name, telephone, ext., fax number, noting date & time of call
Conduct bi-weekly follow-up with payer contact to check on preauth status
Is the preauthorization approved?
YES
NO
Appeal Preauthorization Denial?
STOP
Physician conducts NaviCam® Capsule Endoscopy
Physician/Staff submit claim to payer
Is the payment received?
YES
NO
STOP
Proceed to appeals process
Appeal Level I
1. Obtain copy of denial letter from payer or patient
2. Contact payer for clarification, if needed, or if denial can be corrected by providing info over the phone
3. Speak to utilization review nurse and/or medical director to address reason for denial, if possible
4. Provide the following to the appeals dept: Letter of Medical Necessity (see sample on page 6), Clinical notes, description of procedure (p.14), NaviCam Stomach Capsule description (p.3-4) and clinical information (p.23-27)
Payer Communication Process
1. Follow up with payer contact 10-15 days into the process to check status
2. Follow up with payer contact 20-30 days into the process to check status
3. Continue follow-up until final determination. Most payers will respond with a decision within 30 days.
Is Appeal Level I approved?
NO
Appeal Preauthorization Denial?
YES
Appeal Level II
1. Obtain copy of denial letter from payer or patient
2. Physician may request peer-to-peer phone discussion with payer medical director. Call the number on the denial letter for instructions.
3. Provide the following to the appeals dept: Letter of Medical Necessity and submit additional clinical data documenting patient's condition and necessity for treatment not previously mentioned in correspondence to payer
4. Provide additonal clinical notes and additional clinical data to clarify treatment
5. See Payer Communication Process
NO
STOP
YES
NO
Is Appeal Level II approved?
NO
Appeal Preauthorization Denial?
YES
Appeal Level III
1. Obtain copy of denial letter from payer or patient
2. Appeal Level III typically includes a review from an external medical director
3. Request peer-to-peer phone discusssion with external medical director. Call the number on the denial letter for instructions.
4. May require additonal clinical notes and additional clinical data to clarify patient's condition and medical necessity
5. See Payer Communication Process
YES
Is Appeal Level III approved?
NO
STOP
YES
Patient Action Steps:
If all levels of preauthorization appeals have been denied by the payer, the patient has options in order to obtain treatment:
1. The patient may submit own letter of medical necessity to the payer
2. The patient may choose to pay out-of-pocket for the procedure
3. If the patient is insured under a self-insured (self-funded) health plan, the patient may seek authorization through the employer
4. Patient may contact the Department of Labor
5. Patient my contact State Insurance Commissioner

Each claim must be submitted with the ICD-10-CM codes that reflect the highest level of specificity of the condition of the patient. The following list of diagnosis codes is not intended to be all inclusive. These codes may be appropriate to support medical necessity for the indications in which the NaviCam Stomach Capsule is used:

***ICD-10-CM Diagnosis Codes***

- A04.8 – Helicobacter pylori infection
- C15 – malignant neoplasm of esophagus
- C16 – malignant neoplasm of stomach
- C17 – malignant neoplasm of duodenum
- C86.2 – Intestinal lymphoma
- D48.1 – gastric stromal tumors
- D50 – iron deficiency anemia
- E85.9 – amyloidosis
- K20 – esophagitis
- K21 – gastroesophageal reflux disease
- K22 – other diseases of esophagus
- K25 – gastric ulcer
- K26 – duodenal ulcer
- K27 – peptic ulcer
- K28 – gastrojejunal ulcer
- K29 – gastritis and duodenitis
- K30 – dyspepsia
- K31 – other diseases of stomach and duodenum
- K44.9 – hiatal hernia
- K50 – Crohn's disease
- K52.9 – enteritis
- K58.9 – irritable bowel syndrome
- K90.0 – sprue (Celiac disease, Tropical sprue)
- K92.2 – gastrointestinal hemorrhage, unspecified
- R12 – heartburn

Physicians use Current Procedural Terminology codes to report all their services. These codes are accepted by most payers. Medicare, Medicaid, Tricare, some Workers Compensation programs, and most indemnity insurers use a fee schedule to pay physicians for their professional services, assigning a flat payment amount to each CPT code. Under Medicare's Resource Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the relative value units or RVU, which is the sum of the physician work, practice expense and professional liability insurance multiplied by the geographic practice cost index (GPCI).

Many other payers use Medicare's RBRVS fee schedule or a variation of it. Use of CPT codes is governed by various coding guidelines published by the American Medical Association (AMA) and have input from other sources such as physician societies. In addition, the National Correct Coding Initiative (NCCI), a set of CPT coding edits created and maintained by the Centers for Medicare and Medicaid Services (CMS), has become a national standard.

Inclusion of a CPT, HCPCS, or ICD-10 code does not represent endorsement of any given diagnostic or therapeutic procedure by the bodies that develop the codes (AMA, CMS, and the CDC). The inclusion of the code in CPT, HCPCS, or ICD-10 does not imply that it is covered or reimbursed by any health insurance coverage.



***Possible Procedure Codes***

The CPT codes listed below may be appropriate for the NaviCam Stomach Capsule procedure:

Magnetically Controlled Capsule Endoscopy (MCCE) should be reported using code 0651T
- "Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report."

## Category III Coding Guidelines

Medicare does not establish fees for Category III Codes, so physicians need to request/ negotiate payment for these codes. Coverage of Category III codes is generally based on medical review of documentation submitted.

When CPT code 0651T is used to report the MCCE procedure, it is recommended that the following be considered. A sample letter is provided as a reference when requesting preauthorization of the procedure and submitting a claim.

The following is a list of items that should be provided to the insurance carrier for both preauthorization and claim submission:

- Nature and extent of the procedure performed
- Patient's medical history
- Medical necessity for the procedure
- Complexity of symptoms, final diagnosis, physical findings, concurrent problems, and follow up care
- Detailed description of procedure and supplies
- Preauthorization letter
- NaviCam® Stomach System FDA clearance letter
- NaviCam® Stomach System product information
- Clinical data bibliography
- Physician's recommendation of crosswalk code(s) that compare in terms of time and complexity

***For Claim Submission of MCCE, Include:***

- Manual Claim Form (CMS-1500)
- Special Report Cover Letter
- Operative report
- Nature and extent of the procedure performed
- Patient's medical history
- Medical necessity for the procedure
- Total time, effort, and equipment needed and used
- Complexity of symptoms, final diagnosis, physical findings, concurrent problems, and follow up care
- Detailed description of procedure and instrumentation
- Preauthorization letter
- NaviCam® Stomach System FDA clearance letter
- NaviCam® Stomach System product information
- Clinical data bibliography (see section 8)

***Sample Special Report Cover Letter***

Dear (Contact Name):

On (date of service), I performed a (name of procedure) on the above-mentioned patient. (Patient's Name) was diagnosed with (Diagnosis). This patient also has (List any associated symptoms or co-morbidities). (If applicable, include additional information such as alternative treatments that have failed and what health problems may have occurred if the patient did not undergo the procedure. Describe anticipated outcomes and the medical benefits of the treatment).

This procedure may be reasonably compared to the existing CPT code (code number and description) in terms of physician work and practice expense. (Define what the procedure entailed and how much more/less difficult it was than the comparable CPT code).

My charge for (the comparator CPT code) is $_____. I estimated the charge for the submitted procedure to be (list percentage that current procedure is less or more difficult than the comparator code) for the reasons mentioned above. Therefore, I have submitted a charge of $ _____ for this procedure. Attached, please find a detailed copy of my operative report, office notes, published articles supporting this procedure and a claim form for (patient's name).

Sincerely,

(Physician's Signature)

Practice Name

## FDA

May 2020: FDA De Novo Granted for NaviCam Capsule Endoscope System (https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190037.pdf)

May 2021: FDA 510(k) Clearance for NaviCam Xpress (https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203192.pdf)

October 2023: FDA 510(k) Clearance for Expanded Indications https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231960 Indications for Use:

The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥6 years old with a BMI ≤65 and a waist circumference ≤77 inches. The system can be used in clinics and hospitals, including ER settings.

FDA identifies this generic type of device as:

Magnetically maneuvered capsule endoscopy system. A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

***Sample Preauthorization Letter***

Re: Preauthorization Request for Service

Patient's Name:
Date of Birth:
Subscriber/Policy #:
Group #:

To Whom This May Concern:

This letter is to request approval for the procedure needed for (patient's name) who suffers from (diagnosis). (Patient's name) has suffered from (list all symptoms) since (date), despite efforts to manage (his/her) symptoms using (previous treatments).

(Specific symptoms) are impacting (patient's name) lifestyle, job, family and wellbeing. (Patient's name) symptoms have steadily progressed, and conservative treatment options have failed to alleviate the symptoms. Based on the patient's presentation and physical findings, I am recommending a magnetically controlled capsule endoscopy procedure.

This procedure utilizes precise, multi-dimensional rotation and navigation of the imaging capsule to achieve a complete and accurate examination of the patient's stomach. The procedure requires no anesthesia. I prefer to perform this procedure at (name of facility).

Please advise me immediately if benefits are available for this procedure and/or if additional information is required. Because (patient's name) is in considerable discomfort and (his/her) condition is impacting (his/her) quality of life, we appreciate your immediate attention to this request.

Sincerely,

Physician Name

***Description of Procedure***

CPT Code 0651T – Magnetically controlled capsule endoscopy, esophagus through stomach, including intra-procedural positioning of capsule, with interpretation and report

**Indications for use:** The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥6 years old with a BMI ≤65 and a waist circumference ≤ 77 inches. The system can be used in clinics and hospitals, including ER settings.

The NaviCam® Stomach System is a capsule endoscopy system designed to obtain images of the stomach. It differs from other capsule endoscopy systems, such as these used for small bowel examination, as the NaviCam® Stomach System utilizes magnetic fields to allow the physician to navigate the capsule within the gastric anatomy.

The NaviCam® Stomach System with NaviCam Stomach Capsule consists of an ingestible capsule and external magnetic controller used for visualization of the stomach. The capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is located outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction. The stomach capsule endoscopy system utilizes precise, multi-dimensional rotation and movement, of a robotic arm with adaptive matching, to achieve precise control of the capsule for a complete and accurate examination of the stomach.

***Sample Operative Report (Reference Material Only)***

Please Note: The following sample is for illustrative purposes only and reflects one of several treatment options that may be available in this hypothetical case.

| | |
|---|---|
| Date of procedure: | March 15, 2021 |
| Patient Date of Birth: | November 25, 1960 |
| Physician: | Dr. John Smith |
| Patient Diagnosis: | Hematemesis |
| Procedure: | Magnetically Controlled Capsule Endoscopy of the stomach |
| Complications: | None |
| Indications: | A 35-year-old male with a history of NSAID use and alcohol consumption presents to the Emergency Room with hematemesis. Physical examination reveals normal vital signs without orthotic hypotension. No abdominal guarding, tenderness, rebound, or masses are identified. There are no stigmata of chronic liver disease, jaundice, or ascites. Stool is weakly positive for occult blood. Labs reveal a hematocrit of 10.1gm. Dr. Smith determines that assessment of the upper GI tract should be performed before deciding whether the patient should be admitted for observation vs. discharge to home. |
| Procedure: | Patient is brought to the hospital's NaviCam dedicated procedure room. The patient drinks water with simethicone and then swallows the MCCE capsule. The MCCE capsule is steered by the physician to examine the stomach. Erosive gastritis of the gastric fundus is identified, but no active GI bleeding. Photo documentation is obtained. The MCCE capsule is maneuvered into the duodenum.<br>No abnormalities are identified. Data is downloaded to the workstation and images are reviewed. A prescription for a PPI is ordered, the patient is counseled to cease consumption of NSAID and alcohol, and is discharged with instructions to follow-up with their PCP in the next 1-2 days. |

# SECTION 6: DENIALS

Even with a comprehensive approach to preauthorization, you may occasionally receive denials from health plans. The following guidelines are based on industry-standard appeals processes. Most health plans have a three-level documented appeals process.

If the health plan issues a denial to a preauthorization or a claim, it is advised that you inquire about the plan's appeal process so you can initiate it.

Recommended Steps:

- Request a copy of the denial in writing
- Determine the reason of the denial (coding, technology, or medical necessity)
- Reconsideration – Request a peer-to-peer review – surgeon to health plan Medical Director – focusing on benefits of treatment and its medical necessity
- First Level Appeal – Include a letter of appeal, medical necessity justification, successful outcomes, description of procedure, operative report, and any peer reviewed literature to support your position
- Second Level Appeal – Request a specialty matched external review from a Board-Certified Physician (Gastroenterologist) with experience in diagnostic gastroenterology procedures.
- Third Level Appeal – Request independent external review

The following are examples of an appeal letter and a hypothetical operative report which may be utilized in the appeal process:

- Sample letter of appeal for a predetermination denial
- Sample operative report

***Sample Appeal Letter***

Re: Patient's Name
Date of Birth
Subscriber/Policy #:
Group #:

This is a follow up to my letter of (date of preauthorization request letter) regarding preauthorization of benefits for the above referenced patient. Your previous response indicates that benefits are not available because (reason for denial). I hope the following information clarifies the medical necessity of the procedure I am recom-mending to visualize the gastric cavity for (patient's name)'s (patient's condition/diagnosis).

The MCCE procedure is intended for visualization of the stomach without the need for anesthesia or sedation. For this patient, I prefer to utilize MCCE because:

- MCCE requires virtually no sedation, while endoscopic procedures generally require sedation or anesthesia.
- There is minimal risk of perforation with MCCE, compared to a risk of perforation with the insertion of an endoscope into the esophagus.[1]
- MCCE can navigate a 180° turn to view the esophageal sphincter, while endoscopic view is limited.
- MCCE can view the stomach in its natural state rather than the sedated invasive state, which is important for the diagnosis of motility conditions such as gastroparesis.
- MCCE enables me to actively control the capsule to ensure I see the entire mucosa of the esophagus, stomach, while CE can only rely on natural peristalsis and effects of gravity to move the capsule.

I prefer to perform this procedure at (name of facility).

Therefore, I request that you authorize coverage for this procedure for MCCE billed under CPT 0651T – Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report. Because (patient's name) is in considerable discomfort and (his/her) condition is impacting (his/her) quality of life, we appreciate your immediate attention to this request. If you have any questions concerning this request, please do not hesitate to contact me at
(phone number).

Sincerely,

Physician

1. In the FDA clinical study, no adverse events were reported. In the Comparative Study, among the 350 patients included in the study, adverse events reported did not include perforation.

***Is there a CPT Code that physicians may use to report Magnetically Controlled Capsule Endoscopy?***

Magnetically Controlled Capsule Endoscopy (MCCE) should be reported using code 0651T - "Magnetically controlled capsule endoscopy, esophagus through stomach, including intra-procedural positioning of capsule, with interpretation and report."

***Is preauthorization for the MCCE procedure recommended?***

AnX Robotica recommends following the payer's criteria for the prior authorization of routine and/or emergent services.

***What can I do if the claim submitted for MCCE is denied by the payer?***

Category III Codes will often trigger a request for additional information in the form of a denied claim. There is an appeals process that is designed to provide access to procedures and treatments which are appropriate. Appeals should include documentation to justify use, coverage and payment for the CPT 0651T code including special report, letter and/or clinic notes to support medical necessity, operative note providing nature and extent of patient condition and detailing work performed, resources utilized, and any relevant supporting clinical information. (see section 6)

***What is the expected physician payment for CPT 0651T?***

Category III Codes are not assigned a specific payment by CMS, so physicians need to request appropriate payment for the procedure. This payment may be based on a special report, letter and/or clinic notes to support medical necessity, operative note providing the nature and extent of the patient condition and detailing the work performed, resources utilized, and any relevant supporting clinical information which compares MCCE to other services performed by the physician.

***What additional support can AnX Robotica provide if I have questions?***

AnX has a dedicated Reimbursement Support team to assist with your reimbursement questions. Please contact us at reimbursement@anxrobotics.com

***What is the facility reimbursement for the MCCE procedure?***

| 2024 Medicare National Average Allowable Amount | | | | |
|---|---|---|---|---|
| **CPT Code** | **Description** | **Physician** | **Medicare OPPS Payment** | **Medicare ASC Payment** |
| 0651T | Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report | Request/ Negotiate Appropriate Payment | $863.69 | $646.93 |

# SECTION 8: BIBLIOGRAPHY

The clinical evidence which demonstrates clinical use and efficacy of the NaviCam Capsule Endoscopy System includes 32 peer reviewed publications.

***Summaries of several recent peer-reviewed, clinical publications which describe the MCCE procedure are below:***


1. Liao Z., Hou X., et al. ***Accuracy of Magnetically Controlled Capsule Endoscopy, Compared with Conventional Gastroscopy in Detection of Gastric Diseases;*** *Clin Gastroenterol Hepatol 2016; 14:1266–73*

   **Conclusions:**

   Magnetically Controlled Capsule Endoscopy detects focal lesions in the upper and lower stomach with comparable accuracy with conventional gastroscopy. MCCE is preferred by almost all patients, compared with gastroscopy, and can be used to screen gastric diseases without sedation.

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2. Zhao AJ., Qian YY., Sun H., et al. ***Screening for gastric cancer with magnetically controlled capsule gastroscopy in asymptomatic individuals. Gastrointestinal Endoscopy 2018; 88:466-474***

   **Conclusions:**

   MCCG can detect cancer and benign lesions and is safe and clinically feasible in a large population. Studies of its role in a screening program should be considered.

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3. Nam SJ, Lee HS, Lim YJ. ***Evaluation of Gastric Disease with Capsule Endoscopy.*** *Clin Endosc. 2018;51(4):323-328.*

   **Conclusions:**

   The clinical significance of CE in the evaluation of gastric pathology is very limited. However, due to patient-friendly, non-invasive, and safe features requiring no sedation, trials to develop more sophisticated CE control systems are continuing. In the near future, technical improvements including integration with AI may facilitate the application of CE as an important medical device not only in the small bowel but also for gastric lesion evaluation and management. We dare to predict that the entire gastrointestinal tract can be evaluated with CE (pan-endoscopy) in the future.

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4. Qian Y-Y., et al. ***Preliminary study of magnetically controlled capsule gastroscopy for diagnosing superficial gastric neoplasia. Digestive and Liver Disease, Volume 50, Issue 10, P1041-****1046, October 01, 2018*

   **Conclusion:**

   With good gastric preparation and careful examination of stomach, MCCE is able to detect superficial gastric neoplasms.

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5. Zhang S., Sun T., Xie Y., et al. ***Clinical Efficiency and Safety of Magnetic-Controlled Capsule Endoscopy for Gastric Diseases in Aging Patients: Our Preliminary Experience. Dig Dis Sci*** *64,2911-2922 (2019)*

   **Conclusions:**

   Our preliminary data support that MCCE offers considerable benefit and is general safe for the elderly. We hope such data promote greater awareness of innovative attempts for the specific elderly, and expect multi-center, large-scale trials with randomized controlled design bring optimized strategies for better gastric visibility, efficacy and lower potential risk.

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6. Li J, Ren M. ***Screening value for gastrointestinal lesions of magnetic-controlled capsule endoscopy in asymptomatic individuals. J Gastroenterol Hepatol. 2020 Sep 30. doi: 10.1111/****jgh.15282.*

   **Conclusions:**

   Magnetic-controlled capsule endoscopy could be used as a promising novel screening modality for diagnosis of gastrointestinal lesions in asymptomatic individuals, specifically gastric tumors and precancerous lesions, with the advantages of safety, non-invasiveness, effectiveness, and cost-efficiency

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# Converging Robotics & AI...a new vision of GI diagnostic & therapeutic excellence

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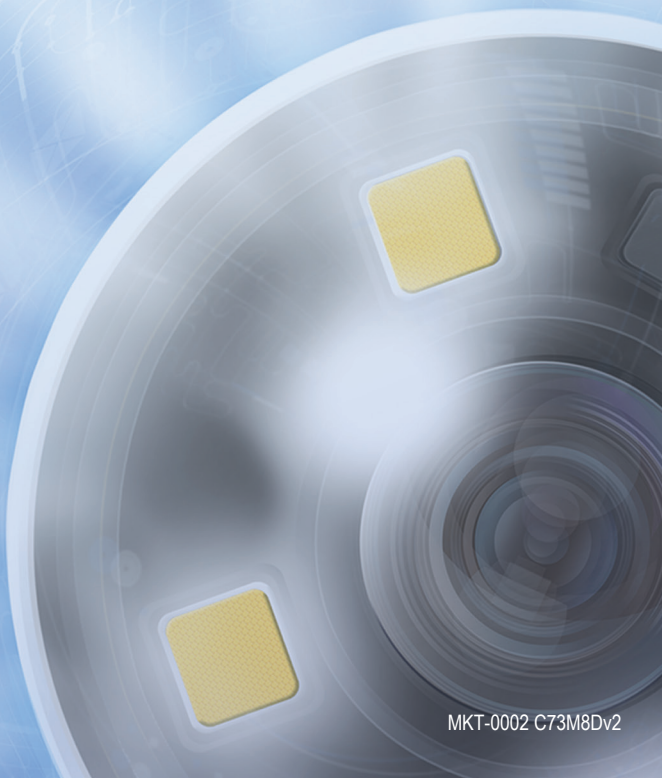

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