Wireless Capsule Endoscopy

Policy Number:	**M020214295**
Effective Date:	**2/14/2002**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **wireless capsule endoscopy (WCE).**

Policy:

General Requirements – Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, Child Health Plus and Essential Plan:

1. Member's clinical documentation or radiographic documentation indicates no obstruction or significant narrowing that might contraindicate use of the capsule.
2. The physician must submit a statement explaining how the results of the wireless capsule endoscopy will specifically alter management of the member.

Note: Due to insufficient peer-reviewed scientific evidence, the following services are considered experimental:

- Patency capsule use to evaluate the patency of the gastrointestinal tract.
- Evaluation of the colon including but not limited to detection of colonic polyps or colon cancer.

Commercial, Self-Funded and Medicare Advantage:
WCE may be considered medically necessary when the following criteria are met:

Gastrointestinal (GI) Bleeding
WCE may be authorized for adult patients with **occult GI bleeding** in two different clinical scenarios.

1. **Chronic Occult GI Bleeding (i.e., no source of bleeding has been identified by colonoscopy and esophagogastroduodenoscopy (EGD)); Must Meet all of the Following Criteria:**
    - Iron deficiency anemia that is not responsive to iron replacement; and
    - Colonoscopy and EGD have failed to reveal a source for bleeding; and
    - Hemorrhoidal bleeding has been ruled out by the requesting provider.

2. **Significant Intermittent GI Bleeding; Must Meet all of the Following Criteria:**
    - Melena or hematochezia on at least two separate occasions; and
    - Decrease in hemoglobin to less than 11; and
    - Colonoscopy and EGD have failed to reveal a source for bleeding; and
    - Hemorrhoidal bleeding has been ruled out by the requesting provider; and
    - In the appropriate clinical setting (active bleeding during the work-up) angiography and or tagged red cell scanning and Meckel scanning (if patient is less than 60 years old) would also have been done. If these diagnostic procedures were performed within six months of the planned WCE, repeat testing is at the discretion of the managing clinician.

Crohn's Disease
WCE may be authorized for patients with **suspected Crohn's disease** who meet **all** the following criteria:

- Persistent abdominal pain and diarrhea; and
- Weight loss or evidence of malnutrition (e.g., hypoalbuminemia, iron deficiency or B12 deficiency); and
- Negative upper and lower endoscopies; and
- Small bowel series shows no evidence of significant narrowing or evidence of fistula; and
- Negative stool cultures.

Diagnosis of Crohn's disease is known but it is necessary to determine whether there is involvement of the small bowel as well.

Crohn's Disease (non-specific type)
WCE may be authorized for a diagnosis of indeterminate Crohn's disease for the following:

- when a diagnosis of colitis of a non-specific type affecting the colon is known, and a more specific diagnosis is sought by evaluating for possible small bowel involvement;

WCE for the Pediatric Member

Pediatric indications for children age 10 and up are the same as those for an adult. Requests for children under age 10 are subject to review by the Medical Director on a case-by-case basis.

Lynch Syndrome

WCE may be used as surveillance in patients with confirmed Lynch syndrome every two to three years.

Familial Adenomatous Polyposis

WCE may be used as surveillance in members diagnosed with familial adenomatous polyposis (FAP) or Peutz-Jeghers syndrome every two to three years.

Suspected Small Bowel Neoplasm

The test is indicated for the detection of neoplasms of the small bowel, when the diagnosis has not been previously confirmed by other studies. The patient must be symptomatic for a neoplasm (e.g., GI bleeding), or have a documented polyposis syndrome that is associated with small bowel neoplasia, or there is other history suggesting the presence of small bowel neoplasia and other diagnostic testing to assess these symptoms must have been performed. WCE may be indicated for the detection of small bowel neoplasm in those patients with documented intussusception of the small bowel, without established etiology. In such instances the requirement for prior examination by upper and lower endoscopies may be waived.

Evaluation Prior to Surgery

Evaluation of extent of small bowel involvement with arteriovenous malformations or lymphangiectasia for patients who are contemplated for surgical resection of the small bowel to control recurrent bleeding or protein loss is reasonable.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

Per New York State criteria:

1. Wireless capsule endoscopy is not payable for patients who have not undergone upper GI (gastrointestinal) endoscopy and colonoscopy within the same spell of illness, which have failed to reveal a source of bleeding.
2. This test is payable only for those patients with documented continuing GI blood loss and anemia secondary to bleeding.
3. This test is not reimbursable for colorectal cancer screening.
4. The test is payable only for services using FDA (Food and Drug Administration) approved devices.
5. This test is not reimbursable for the confirmation of lesions or pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum).
6. This test is not payable for patients with hematemesis.
7. This test is covered only when performed by a gastroenterologist.
8. It is expected that the test will be performed only once during any episode of illness.
9. Ingestion of the capsule does not constitute an Evaluation and Management (E &M) service billing.

Diagnoses supporting medical necessity:

1. Diverticulosis of small intestine with hemorrhage

2. Diverticulitis of small intestine with hemorrhage
3. Angiodysplasia of intestine with hemorrhage
4. Blood in stool
5. Hemorrhage of gastrointestinal tract, unspecified
6. Nonspecific abnormal findings in stool contents

Background
The Food and Drug Administration (FDA) approved the device in 2001 as a diagnostic test for visualization of small bowel pathology in conjunction with conventional diagnostic studies. The FDA approval was based primarily upon results of use of WCE in patients with occult gastrointestinal (GI) bleeding. In 2003, the FDA removed the "adjunctive tool" requirement, allowing use of WCE as a primary diagnostic tool for the small bowel.

While the outcomes of the procedure appear to be promising, the criteria for authorization of this procedure should currently be restricted to those patients for whom the available evidence would suggest the most chance of successful outcomes, i.e., those patients with occult GI bleeding. There is also some evidence that WCE may be useful in some patients suspected of having Crohn's disease.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No☐

Pre-authorization is required for this service. Requests must come from a gastroenterologist or other physician who is credentialed to perform both colonoscopy and upper GI endoscopy.

Definitions

Colonoscopy is an exam that views the inside of the colon (large intestine) and rectum, using a tool called a colonoscope. The colonoscope has a small camera attached to a flexible tube that can reach the length of the colon.

Esophagogastroduodenoscopy (EGD) is a test to examine the lining of the esophagus, stomach, and first part of the small intestine using an endoscope. The endoscope is a flexible tube with a light and camera at the end.

Meckel scan is a test that uses technetium-99m pertechnetate and has a high sensitivity (75 to 100 percent) for identifying gastric mucosa in the small bowel but cannot confirm the identified lesion as the source of bleeding.

Peutz-Jeghers syndrome (PJS) is characterized by the development of noncancerous growths called hamartomatous polyps in the gastrointestinal tract (particularly the stomach and intestines) and a greatly increased risk of developing certain types of cancer including cancers of the gastrointestinal tract, pancreas, cervix, ovary, and breast.

Tagged red cell scan, also known as RBC nuclear scan, uses small amounts of radioactive material to mark (tag) red blood cells (RBCs). The patient is then scanned to see the cells and track how they move through the body to a site of bleeding.

Wireless capsule endoscopy (WCE) is a procedure in which a patient swallows a capsule-sized camera that transmits video images of the gastrointestinal tract to an external receiver. It is a diagnostic test for visualization of small bowel pathology in conjunction with conventional diagnostic studies.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
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