Clinical Policy: Wireless Capsule Endoscopy

Reference Number: WNC.CP.261 Coding Implications
Last Review Date: 11/24 Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

This policy describes the medical necessity criteria for Wireless Capsule Endoscopy.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover Wireless Capsule Endoscopy when the member meets the following specific criteria:

- **A.** For undiagnosed obscure gastrointestinal bleeding, **ALL** of the following criteria must be met:
  1. GI bleeding is significant as demonstrated by **one** of the following:
     a. An acute drop in hemoglobin/hematocrit;
     b. Unexplained recurrent or persistent iron deficiency anemia demonstrated by low serum iron studies or low serum ferritin level;
     c. Persistently positive fecal occult blood test; **OR**
     d. Visible bleeding with no bleeding source found at original endoscopy;
  2. Failure of previous diagnostic studies to diagnose the source of GI bleeding, including upper and lower GI endoscopy within the past 12 months, esophagogastroduodenoscopy (EGD) or colonoscopy; **AND**
  3. Source of GI bleeding is thought to be in the upper gastrointestinal tract.
- **B.** For suspected Esophageal Varices
- **C.** For suspected Barrett's Esophagus
- **D.** For suspected Crohn's Disease when the diagnosis has not been established by upper and lower endoscopy studies, **ALL** of the following must be met:
  1. Persistent abdominal pain of greater than 4 weeks;
  2. Persistent diarrhea with one or more signs of inflammation (fever, elevated white blood cell count, elevated erythrocyte sedimentation rate, or bleeding)
  3. Unintentional weight loss;
  4. Negative stool cultures; **AND**
  5. Negative upper and lower endoscopy studies.
- **E.** For suspected Celiac disease with a positive serology and negative biopsy, **or**

F. For surveillance of the small intestine of members with hereditary polyposis syndromes.

NOTE: *The wireless capsule must be approved by the Federal Drug Administration (FDA).*

II. WellCare of North Carolina® shall not cover capsule system testing or radiography to evaluate GI patency prior to wireless capsule endoscopy.

III. WellCare of North Carolina® shall not cover wireless capsule endoscopy in following situations:
- **A.** Undiagnosed obscure GI bleeding when criteria in I.A. is not met;
- **B.** Known or suspected gastrointestinal obstruction, stricture, fistulae, known bowel disease;
- **C.** For a diagnosis of suspected:
  1. Crohn's Disease when criteria I.D. above is not met.
  2. Irritable Bowel Syndrome (IBS);
  3. Celiac disease when criteria I.E., is not met;
  4. Gastric or intestinal neoplasm; **OR**
  5. Intestinal polyps when criteria I.F is not met.
- **D.** Recurrent intussusception;
- **E.** Duodenal lymphocytosis;
- **F.** Surveillance of the small intestine for a member with hereditary polyposis syndrome;
- **G.** As a first-line diagnostic tool for diffuse abdominal pain;
- **H.** As a replacement for colonoscopy for colon cancer screening as part of United States Preventative Services Task Force (USPSTF) recommendation; **OR**
- **I.** When criteria listed in Criteria I of this policy, is not met.

IV. In addition to criteria listed in Criteria III of this policy, WellCare of North Carolina® shall not cover wireless capsule endoscopy when the member:
- **A.** Is pregnant; **OR**
- **B.** Has A cardiac pacemaker, defibrillator, spinal cord stimulator, or other implanted electromagnetic device.

Background[1]

I. Description of the Procedure:
- **A.** The member must swallow a tiny capsule that contains a data transmitter, battery, antenna, disposable light source, and tiny color video camera in order to undergo wireless capsule endoscopy (WCE). The self-contained capsule is constructed from a

biocompatible polymer that is resistant to the digestive fluids found in the gastrointestinal (GI) tract and is sealed with careful care. After swallowing the capsule, the GI tract's normal contraction and relaxation forces the capsule forward. The member wears a data recorder around their waist the whole time, capturing and storing pictures sent by the capsule's camera. Following the surgery, a computer workstation is attached to the member's data recorder, allowing the pictures to be downloaded, examined, and interpreted by the physician. The process takes about five minutes to observe the mucosa of the esophagus and about eight hours to observe the mucosa of the intestine. The capsule is excreted naturally from the body and is made to be thrown away.

II. Definitions

A. **Endoscopy**
An endoscopy is the inspection of body organs or cavities by use of the endoscope.

B. **Gastrointestinal imaging or visualization**
Gastrointestinal imaging or visualization is a visual display of structural or functional patterns of the GI system as a whole or any of its parts or tissues for diagnostic evaluation or imaging of anatomical structures. This includes measuring physiologic and metabolic responses to physical and chemical stimuli.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	07/21	08/21
Reviewed CPT code.	06/22	08/22
Annual Review. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23
Annual Review. Removed HCPCS & ICD-10 codes tables.	05/24	05/24
Annual Review. Criteria I. text updated with no effect on criteria. Under Criteria I.F. Added a Note that the wireless capsule must be approved by the Federal Drug Administration (FDA). Criteria II and III, Reformatted and clarified the information into a list form. Criteria IV. Added text "In addition to criteria listed in Criteria III of this policy, WellCare of North Carolina® shall not cover wireless capsule endoscopy when the member: : A. Is Pregnant; or B. Has a cardiac pacemaker, defibrillator, spinal cord stimulator, or other implanted electromagnetic device." Background I. Updated the description of the procedure. Background II. Added Definitions for Endoscopy and Gastrointestinal imaging or visualization. Removed Medicaid and health choice verbiage from References.	11/24	11/24

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 1A-31 Wireless Capsule Endoscopy. Program Specific Clinical Coverage Policies NC Medicaid (ncdhhs.gov). Published September 1, 2024. Accessed September 12, 2024.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:

https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.