

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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1.0 Description of the Procedure, Product, or Service

The beneficiary 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 beneficiary 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 beneficiary'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.

1.1 Definitions

Endoscopy

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

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.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid policies)

- 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.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.

2.2 Special Provisions

2.2.1 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.

b. 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/>

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid shall cover Wireless Capsule Endoscopy when the beneficiary 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 a beneficiary with hereditary polyposis syndromes.

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

3.2.2 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid shall not cover capsule system testing or radiography to evaluate GI patency prior to wireless capsule endoscopy. Medicaid shall not cover wireless capsule endoscopy in following situations:

- a. undiagnosed obscure GI bleeding;
- b. Known or suspected gastrointestinal obstruction, stricture, fistulae, known bowel disease;
- c. For a diagnosis of suspected:
 - 1. Crohn's disease or irritable bowel syndrome (IBS);
 - 2. esophageal varices;
 - 3. Barrett's esophagus;

4. Celiac disease;
5. gastric or intestinal neoplasm; or
6. intestinal polyps.
- d. Recurrent intussusception;
- e. Duodenal lymphocytosis;
- f. Surveillance of the small intestine for a beneficiary 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 in **Subsection 3.2** is not met.

4.2.2 Medicaid Additional Criteria Not Covered

In additional to criteria listed in **Subsection 4.2.1**, Medicaid shall not cover wireless capsule endoscopy when the beneficiary:

- a. is Pregnant; or
- b. has a cardiac pacemaker, defibrillator, spinal cord stimulator, or other implanted electromagnetic device.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for Wireless Capsule Endoscopy. The provider shall obtain prior approval before rendering Wireless Capsule Endoscopy.

Prior approval (PA) is not required when the procedure is initiated in the emergency department due to a potentially life-threatening condition and the criteria in **Subsection 3.2.1** is met.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

Emergency Procedure

Medicaid shall require that the provider submit an electronic request for prior approval with supporting documentation, through the NCTracks provider portal within 72 hours of the date of service.

6.0 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 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).

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 2012

Revision Information:

| Date | Section Revised | Change |
|------------|------------------------------|---|
| 1/1/12 | Throughout | Initial promulgation current coverage of CPT 91110 with prior authorization in compliance with SL2011-0145 HB 200 |
| 3/12/12 | Throughout | Technical changes to merge Medicaid and NCHC current coverage into one policy. |
| 10/01/2015 | All Sections and Attachments | Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable. |
| 03/15/2019 | Table of Contents | Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.” |
| 03/15/2019 | All Sections and Attachments | Updated policy template language. |
| 12/04/2019 | Table of Contents | Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.” |
| 12/04/2019 | Attachment A | Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines. |
| 01/01/2021 | Section 5.1 | Added, “unless the procedure was initiated in the emergency department as a result of a potentially life-threatening condition and the criteria in subsection 3.2.1 are met. In the event of emergency service, Medicaid and NCHC shall require that the provider submit an electronic request for prior approval with supporting documentation through the NCTracks provider portal within 72 hours of the date of service.” |
| 08/15/2023 | All Sections and Attachments | Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 08/15/2023 with an effective date of 4/1/2023. |

| Date | Section Revised | Change |
|-------------|------------------------|--|
| 12/15/2023 | | Fixed minor formatting issue, posting and amended date not changed. |
| 09/01/2024 | Section 1.0 | Updated the description of the procedure. |
| 09/01/2024 | Subsection 3.2.1 | Added text to align with policy template. Added a Note that the wireless capsule must be approved by the Federal Drug Administration (FDA). |
| 09/01/2024 | Subsection 4.2.1 | Reformatted and clarified the information into a list form. |
| 09/01/2024 | Subsection 4.2.2 | Added text “in addition to criteria listed in Subsection 4.2.1, Medicaid shall not cover wireless capsule endoscopy for beneficiaries who are: a. Pregnant; or have a cardiac pacemaker, defibrillator, spinal cord stimulator, or other implanted electromagnetic device. |
| 09/01/2024 | Subsection 5.1 | Added text to align with policy template. |
| 09/01/2024 | Throughout | Corrected punctuation, grammar and formatting. |

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks 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

Professional (CMS-1500/837P 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.

| CPT Code(s) |
|-------------|
| 91110 |

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

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

1 unit= 1 procedure with physician interpretation and report

F. Place of Service

Inpatient hospital, Outpatient hospital.

G. Co-payments

For Medicaid refer to the NC Medicaid State Plan:

<https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>