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1.0 Description of the Procedure, Product, or Service

Wireless capsule endoscopy allows for direct visualization and intervention in the gastrointestinal (GI) tract. Imaging of the GI tract is essential in the diagnosis of GI diseases. Wireless capsule endoscopy is performed using an endoscopy video camera to take thousands of pictures of the esophagus, stomach and small intestine. The endoscopy video camera sits inside a vitamin-sized capsule that is swallowed. The capsule moves passively down the digestive tract, does not inflate the bowel, and images the mucosa in the collapsed state. The endoscopy video camera uses wireless radio transmission to send the images from inside the GI tract to a receiving recorder device that the beneficiary wears around the waist. The receiving device also contains some localizing antennae sensors that can roughly gauge where the images were taken in the GI tract. The images are downloaded onto a workstation for interpretation by qualified providers.

1.1 Definitions

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

Gastrointestinal imaging/visualization is 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; 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 and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

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

- a. **Medicaid**
None Apply.
- b. **NCHC**
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: <http://www.ncdhhs.gov/dma/epsdt/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary

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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall cover wireless capsule endoscopy when is determined to be medically necessary and the criteria are met for clinical scenarios under **ANY** item a, b, c, d, e, or f below:

- 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 beneficiaries with hereditary polyposis syndromes.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC 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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC does not cover wireless capsule endoscopy in the following situations:

- a. Wireless capsule endoscopy for undiagnosed obscure GI bleeding or for diagnosis of suspected Crohn's disease is considered to be not medically necessary when all the criteria in **Subsection 3.2.a** (GI bleeding) or **Subsection 3.3.d** (Crohn's disease) are not met.
- b. Wireless capsule endoscopy for any indication other than undiagnosed obscure GI bleeding, diagnosis of suspected esophageal varices, suspected diagnosis of Barrett's esophagus, diagnosis of suspected Crohn's disease, diagnosis of suspected Celiac disease, or for surveillance of the small intestine of beneficiaries with hereditary polyposis syndromes is considered to be experimental / investigational including the following:
 - 1. When the test is performed for screening.
 - 2. When used as an initial test in diagnosing gastrointestinal bleeding.
 - 3. When used as an initial test in evaluating abdominal pain.
 - 4. When used for evaluation of the esophagus for diseases other than esophageal varices and Barrett's esophagus.
 - 5. When used for the evaluation of the extent of involvement of known Crohn's disease.
 - 6. When used for the evaluation of the extent of involvement of known Celiac disease.
 - 7. When used for the evaluation of other gastrointestinal diseases including irritable bowel syndrome, small bowel neoplasm, recurrent intussusception, and duodenal lymphocytosis.
 - 8. When used for the evaluation of the colon for diseases, including the detection of colorectal polyps or cancer.
 - 9. When used in confirming pathology identified by other diagnostic means.
- c. Wireless capsule endoscopy for persons with known or suspected gastrointestinal obstruction, strictures, or fistulae.
- d. Wireless capsule endoscopy for follow-up for persons with known small bowel diseases.
- e. Patency capsule system used to evaluate patency of the GI tract prior to wireless capsule endoscopy or for any other indication.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

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 and NCHC shall require prior approval for wireless capsule endoscopy. The provider shall obtain prior approval before rendering wireless capsule endoscopy.

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

None Apply.

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 or NCHC 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:
- All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
 - All DMA'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. |

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, 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 Medicaid State Plan, Attachment 4.18-A, page 1, located at <http://www.ncdhhs.gov/dma/plan/sp.pdf>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

H. Reimbursement

Providers shall bill their usual and customary charges.

For a schedule of rates, see: <http://www.ncdhhs.gov/dma/fee/>