Table of Contents

1.0 Description of the Procedure, Product, or Service 1
1.1 Definitions 1

2.0 Eligibility Requirements 1
2.1 Provisions 1
2.1.1 General 1
2.1.2 Specific 2
2.2 Special Provisions 2
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age 2
2.2.2 EPSDT does not apply to NCHC beneficiaries 3
2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age 3

3.0 When the Procedure, Product, or Service Is Covered 3
3.1 General Criteria Covered 3
3.2 Specific Criteria Covered 4
3.2.1 Specific criteria covered by both Medicaid and NCHC 4
3.2.2 Medicaid Additional Criteria Covered 4
3.2.3 NCHC Additional Criteria Covered 4

4.0 When the Procedure, Product, or Service Is Not Covered 4
4.1 General Criteria Not Covered 4
4.2 Specific Criteria Not Covered 4
4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC 4
4.2.2 Medicaid Additional Criteria Not Covered 5
4.2.3 NCHC Additional Criteria Not Covered 5

5.0 Requirements for and Limitations on Coverage 5
5.1 Prior Approval 5
5.2 Prior Approval Requirements 5
5.2.1 General 5
5.2.2 Specific 5
5.3 Additional Limitations or Requirements 6

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service 6
6.1 Provider Qualifications and Occupational Licensing Entity Regulations 6
6.2 Provider Certifications 6

7.0 Additional Requirements 6
7.1 Compliance 6

8.0 Policy Implementation and History 7

Attachment A: Claims-Related Information 8

A. Claim Type 8
B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) 8
C. Code(s) 8
D. Modifiers 9
E. Billing Units 9
F. Place of Service 9
G. Co-payments 9
H. Reimbursement 9

1.0 Description of the Procedure, Product, or Service

Clostridium difficile is a disease-causing bacterium that can infect the large bowel and cause colitis.

Fecal microbiota transplantation (FMT) is the introduction of saline-diluted fecal matter (e.g. fecal suspension) derived from a healthy human donor into the gastrointestinal (GI) tract of an individual diagnosed with recurrent clostridium difficile infection (CDI), who has failed multiple attempts at conventional antibiotic therapy.

Clostridium difficile recurrence is defined by complete abatement of CDI symptoms while on appropriate therapy, followed by subsequent reappearance of diarrhea and other symptoms after treatment has been stopped. Recurrence must be distinguished from persistent diarrhea without resolution during initial therapy, which prompts an evaluation for other causes.

Recurrent clostridium difficile is associated with a decrease in fecal microbial diversity deficient in bacteroides and firmicutes, both of which generally dominate within the gut. Transplantation of stool from a healthy human donor to an individual with recurrent clostridium difficile restores the microbial deficiency and breaks the cycle of recurrence.

Fecal microbiota transplantation involves the restoration of the colonic flora by introducing healthy bacterial flora through infusion of stool by either retention enema, nasogastric tube, nasoduodenal tube, nasojejunal tube, colonoscope, an upper tract endoscope, or a combination of upper and lower approaches obtained from a healthy human donor.

Commonly, gastroenterologists recommend that fecal donors be healthy family members (i.e., parents, siblings, adult children of older patients) or spouses or significant partners who have common genetic and environmental factors.

1.1 Definitions

None Apply.

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**.

CPT codes, descriptors, and other data only are copyright 2014 American Medical Association. All rights reserved. Applicable FARS/DFARS apply.

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**
Refer to **Subsection 3.2.2**.

b. NCHC
NCHC beneficiaries are not eligible for FMT.

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 a Medicaid Beneficiary 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

None Apply.

3.2.2 Medicaid Additional Criteria Covered

Medicaid shall cover FMT when:

a. the beneficiary is 21 years of age and older;
b. the beneficiary has had at least three episodes of recurrent CDI despite the standard antibiotic therapy;
c. the beneficiary is not immunocompromised;
d. an informed consent has been obtained; AND
e. the appropriate donor stool screening has been completed:
    1. screening for transmissible bloodborne diseases or other diseases associated with microflora changes (e.g., irritable bowel syndrome, constipation);
    2. screening for transmissible pathogens;
    3. donor has not had antibiotic therapy for at least three months prior to donation; and
    4. donor shall not ingest foods the beneficiary is allergic to.

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 a Medicaid Beneficiary 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

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

Medicaid shall not cover **FMT** in the following situations:

a. when a beneficiary is under 21 years of age;
b. when an attempt to treat the recurrent CDI with antibiotic(s) was not tried and was not successful, **before** performing fecal microbiota transplantation;
c. for inflammatory bowel disease;
d. for ulcerative colitis;
e. for Crohn's disease;
f. for irritable bowel disease; or
g. for refractory constipation.

Note: In the absence of an alternative diagnosis, the beneficiary shall be considered to have a refractory illness.

4.2.3 NCHC Additional Criteria Not Covered

a. None Apply for **FMT**.
b. 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 a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for **FMT**. The provider shall obtain prior approval before rendering **FMT**.

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.

5.3 Additional Limitations or Requirements

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

Gastroenterologists with specialized training in FMT shall perform this service and services related to FMT.

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 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 and History

Original Effective Date: June 1, 2015

History:

Date	Section or Subsection Amended	Change
06/01/2015	All Sections and Attachment(s)	New 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)

Institutional (UB-04/837I 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.

ICD-10-CM Code(s)
A04.7

C. Code(s)

Provider(s) shall select 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), ICD-9-CM procedure codes, 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.

HCPCS Code(s)
G0455

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

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Clinic, Outpatient hospital, Inpatient 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

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: http://www.ncdhhs.gov/dma/fee/