DRAFT

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.

Table of Contents

1.0 Description of the Procedure, Product, or Service 1
1.1 Definitions 1
Fertility Preservation Services 1
Medical Noncompliance 1
Psychosocial History 2
United States Food & Drug Administration (U.S. FDA) 2

2.0 Eligibility Requirements 2
2.1 Provisions 2
2.1.1 General 2
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

3.0 When the Procedure, Product, or Service Is Covered 3
3.1 General Criteria Covered 4
3.2 Specific Criteria Covered 4
3.2.1 Specific criteria covered by Medicaid 4
3.2.2 Medicaid 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 5
4.2.1 Specific Criteria Not Covered by Medicaid 5
4.2.2 Medicaid 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 6
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 and Related Health Problems, 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

DRAFT

Related Clinical Coverage Policies

Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:
2A-3 Out of State Services
1A-39 Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

1.0 Description of the Procedure, Product, or Service

Human gene therapy aims to manipulate gene expression or alter cellular properties for therapeutic purposes.

Gene therapy involves modifying a beneficiary's genetic makeup to combat or eradicate diseases. This can be achieved through various methods:

a. Replacement of a defective gene with a healthy version.
b. Deactivation of a malfunctioning gene.
c. Introduction of a new or modified gene to address a specific condition.

Gene therapy is currently under investigation for treating a range of illnesses, including cancer, genetic disorders, and infectious diseases.

Different types of gene therapy products are being explored, such as:

a. Plasmid DNA: Circular DNA molecules engineered to transport therapeutic genes into human cells.
b. Viral vectors: Modified viruses utilized to deliver genetic material into cells after being rendered non-infectious.
c. Bacterial vectors: Modified bacteria employed as carriers to transport therapeutic genes into human tissues.
d. Human gene editing technology: Used to disrupt harmful genes or repair mutated ones.
e. Patient-derived cellular gene therapy products: Cells extracted from the patient, genetically altered (often using viral vectors), and reintroduced into the patient.

Gene therapy products fall under the regulatory purview of the FDA's Center for Biologics Evaluation and Research (CBER). Prior to conducting clinical trials in the United States, investigational new drug applications (INDs) must be submitted for human clinical studies. Furthermore, the marketing approval of gene therapy products necessitates the submission and approval of a biologics license application (BLA).

1.1 Definitions

Fertility Preservation Services

Fertility preservation is the process of safeguarding or storing eggs, sperm, or reproductive tissue to enable a beneficiary to have biological children in the future.

Medical Noncompliance

Medical noncompliance, also known as nonadherence, refers to a beneficiary's failure to follow prescribed medications or a recommended treatment plan. This can also involve neglecting other health-improving measures, such as lifestyle changes or dietary adjustments.

Psychosocial History

A psychosocial history assessment is a detailed and comprehensive evaluation of a beneficiary's physical, mental, and emotional well-being, as well as their functional abilities within their community and self-perception. Typically conducted by social workers and medical professionals, this assessment gathers essential information about a beneficiary to understand their current and potential future behaviors. It plays a crucial role in health care programs, aiding in the development of an effective management and action plan for the medical team.

United States Food & Drug Administration (U.S. FDA)

The responsibility of safeguarding public health falls on the Food and Drug Administration (FDA). This entails guaranteeing the safety, effectiveness, and reliability of both human and veterinary drugs, biological products, and medical devices. Additionally, the FDA ensures the safety of the nation's food supply, cosmetics, and items emitting radiation.

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. <u>Medicaid</u>
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 a Medicaid Beneficiary 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 Cell & Gene Therapies when the beneficiary meets the following specific criteria:

a. The Cell or Gene Therapy has received approval from the United States Food & Drug Administration (U.S. FDA);
b. The Cell or Gene Therapy is administered per U.S. FDA approved guidelines regarding:
    1. Indications and usage;
    2. Dosage and administration;
    3. Dosage forms and strengths; and
    4. Warnings and precautions;
c. The administration of the Cell or Gene Therapy occurs at a Qualified Treatment Center (QTC) that has received approval for administering the Cell or Gene Therapy.

3.2.2 Medicaid Additional Criteria Covered

In addition to the specific criteria covered in **Subsection 3.2.1** of this policy, Medicaid shall cover Non-Emergency Medical Transportation (NEMT) to Medicaid beneficiaries with transportation to medical appointments. The NEMT policy is located at https://medicaid.ncdhhs.gov/NEMT-policy. Local Departments of Social Services provide NEMT services for NC Medicaid Direct and the Eastern Band of Cherokee Indians (EBCI) Tribal Option members.

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 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 Cell & Gene Therapies for **ANY** one of the following:

a. The Cell or Gene Therapy has not received approval from the U.S. FDA;
b. The Cell or Gene Therapy is being administered outside U.S. FDA guidelines regarding:
    1. Indications and usage;
    2. Dosage and administration; or
    3. Dosage forms and strengths;
c. The Cell or Gene Therapy is being administered at a facility that has not been approved as a QTC for that therapy;
d. Repeat treatment in beneficiaries who have received the same or another Cell or Gene Therapy previously;
e. When the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-infusion medical care; or
f. When there is current beneficiary or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.2.2 Medicaid Additional Criteria Not Covered

In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, Medicaid shall not cover:

a. Fertility preservation services associated with Cell & Gene Therapy administration;
b. Non-Emergency Medical Transportation (NEMT) for fertility preservation service appointments.

NOTE: Centers for Medicare and Medicaid Services (CMS) will require participating manufacturers to provide payment for fertility preservation services for beneficiaries who receive a Cell & Gene Therapy.

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 Cell & Gene Therapies. The provider shall obtain prior approval before rendering Cell & Gene Therapies. Refer to https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugs-criteria-new-format.html for a list of Cell & Gene Therapies that require prior approval (PA). The website lists the medical necessity criteria for coverage for each Cell or Gene Therapy that requires prior approval.

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 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

The Cell & Gene Therapy must be from a manufacturer enrolled in the Medicaid Drug Rebate Program.

6.2 Provider Certifications

a. Cell & Gene Therapies are exclusively offered at Qualified Treatment Centers (QTC). Each QTC undergoes a meticulous selection process, focusing on their proficiency in specialties like sickle cell disease, transplantation, cellular, and genetic therapy. These centers are equipped with trained personnel to deliver Cell & Gene Therapies effectively. Providers must be qualified to administer Cell & Gene Therapies. Treatment centers must offer appropriate multidisciplinary care, including mental health, substance use disorder (SUD) treatment, pain management, and case management.
b. Providers must meet minimum T-MSIS data requirements.

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;
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); and

c. Data reporting and specific claims submission requirements as defined by the State.

8.0 Policy Implementation and History

Original Effective Date: Month Day, Year

History:

Date	Section or Subsection Amended	Change
	All Sections and Attachment(s)	New Clinical Coverage Policy for U.S. FDA approved Cell & Gene Therapies.

DRAFT

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

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.

a. Provider(s) shall file inpatient claims for Cell & Gene Therapy with the product-specific ICD-10 PCS code, if one has been assigned. If a product-specific ICD-10 PCS has not been assigned, provider(s) shall file inpatient claims with the most specific available billing code.
b. Provider(s) shall include the prior authorization (PA) number on the claim.
c. Provider(s) shall attach invoice from manufacturer of the Cell & Gene Therapy.

ICD-10 PCS Code(s)
XW133H9
XW143H9

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.

HCPCS Code(s)
J3590

a. Provider(s) shall file outpatient claims for Cell & Gene Therapy with the product-specific HCPCS code for the Cell & Gene Therapy. If the Cell & Gene Therapy has been approved by

the U.S. FDA but has not yet been assigned a product-specific HCPCS code, the provider shall use HCPCS J3590 (UNCLASSIFIED BIOLOGICS).

b. Provider(s) shall include the prior authorization (PA) number on the claim.
c. Provider(s) shall attach invoice from manufacturer of Cell & Gene Therapy.

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

Inpatient, Outpatient.

G. Co-payments

For Medicaid refer to 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//

Inpatient Hospital Services: Institutional Claim (UB-04 form/837I transaction)

1. In accordance with the State Plan, the inpatient stay, surgical procedure, and other appropriate inpatient services for Cell & Gene Therapies will be reimbursed using the existing diagnosis-related group (DRG) payment methodology and will be based on the primary diagnosis code and grouped to the appropriate DRG. The PA number should be included on the claim.
2. The product itself should not be submitted on the inpatient claim but submitted via invoice with the required PA number and will be reimbursed at cost (no markup) just as we adjudicate other manually priced services.
3. Refer to the High-Cost Reimbursement Policy located at:

Provider Reimbursement must provide language for outpatient, refer to inpatient criteria in Attachment A: H