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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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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
11A-14 Placental and Umbilical Cord Blood as a Source of Stem Cells
11A-17 CAR T-Cell Therapy
11B-3 Islet Cell Transplantation
11B-9 Thymus Tissue Implantation

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; or
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, including:

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; and
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. The marketing approval of gene therapy products necessitates the submission and approval of a biologics license application (BLA).

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1.1 Definitions

Candidate Beneficiary
A **Candidate Beneficiary** is a beneficiary who meets all of the following criteria:
a. They have a documented medical diagnosis of sickle cell disease (SCD).
b. Their primary payer for a **State-Selected Model Drug** is the State Medicaid program.

Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access Model
The CMS Cell and Gene Therapy (CGT) Access Model is designed to enhance the lives of Medicaid beneficiaries with rare and severe conditions by improving access to potentially life-changing treatments. While these therapies have high initial costs, they offer the potential to lower long-term health care expenses by targeting the root causes of disease, lessening illness severity, and decreasing health care usage. At first, the model will prioritize gene therapy treatments for beneficiaries with sickle cell disease, a genetic blood disorder that predominantly impacts Black Americans.

CMS-Designated Patient Registry
A **CMS-designated patient registry** is a data collection system identified or approved by the Centers for Medicare and Medicaid Services (CMS) for tracking patient outcomes, safety, and other relevant clinical information related to a specific treatment. For the **CMS Cell and Gene Therapy (CGT) Access Model**, providers administering **State-Selected Model Drugs** must participate in these registries, ensuring compliance with CMS guidelines and contributing to the evaluation of treatment effectiveness and long-term patient impact.

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.

Model Beneficiary
A **Model Beneficiary** is a **Candidate Beneficiary** who meets all of the following conditions:
a. They have received an infusion of a **State-Selected Model Drug**.
b. Their primary payer for the infused **State-Selected Model Drug** is the State Medicaid program.
c. At the time of infusion, a Value-Based Purchasing (VBP) Supplemental Rebate Agreement (SRA) between the state and the drug manufacturer is in effect.
d. If the beneficiary is enrolled in either a Managed Care Plan (MCP) or Medicaid Fee-for-Service (FFS) at the time of infusion, their coverage must be included under the terms of the VBP SRA between the manufacturer and the state on that date.

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Model Drug
A **Model Drug** refers to an FDA-approved gene therapy specifically indicated for the treatment of sickle cell disease (SCD). It is a therapy for which the Centers for Medicare and Medicaid Services (CMS) and the manufacturer have agreed upon key terms through negotiation.

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.

Qualified Treatment Center (QTC) or Authorized Treatment Center (ATC)
A Qualified or Authorized Treatment Center is a specialized healthcare facility that has met specific manufacturer (as described in 42 C.F.R. § 447.502) and regulatory requirements to administer certain advanced therapies, such as gene or cell-based treatments. These centers have undergone extensive training, maintain the necessary infrastructure, and adhere to strict protocols to ensure the safe and effective delivery of these therapies. They are typically designated by the therapy manufacturer and may be subject to ongoing oversight to maintain compliance with required standards.

Sickle Cell Disease (SCD)
SCD stands for **sickle cell disease**, an inherited genetic blood disorder characterized by the production of abnormal sickle-shaped red blood cells due to the presence of hemoglobin S (HbS). These rigid and sticky cells can obstruct blood flow, leading to pain, anemia, and severe complications.

State-Selected Model Drug
A **State-Selected Model Drug** in the context of the CMS Cell and Gene Therapy (CGT) Access Model refers to a specific cell or gene therapy chosen by a state to be included in the Model. These therapies are typically high-cost treatments aimed at addressing rare or severe diseases. Under the CGT Access Model, states collaborate with the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these transformative treatments. A **State-Selected Model Drug** is a **Model Drug** for which the state has chosen to enter into a Value-Based Purchasing (VBP) Supplemental Rebate Agreement (SRA) with the manufacturer, reflecting the key terms for the **Model Drug**. Providers administering these therapies must participate in CMS-designated patient registries and follow specific guidelines, including patient counseling for CMS-specified studies. **NC Medicaid's State-Selected Model Drugs are LYFGENIA (lovotibeglogene autotemcel) and CASGEVY (exagamglogene autotemcel).**

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Supplemental Rebate Agreement (SRA)
"**SRA**" means CMS-authorized supplemental rebate agreement as described in 42 C.F.R. § 447.502.

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.

Value-Based Purchasing (VBP)
"**VBP**" means value-based purchasing arrangement as described in 42 C.F.R. § 447.502.

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 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 the U.S. FDA approved label 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) or Authorized Treatment Center (ATC) that has received approval for administering the Cell or Gene Therapy, if required by the manufacturer.

Note: If prior approval (PA) criteria have been established for a Cell or Gene Therapy (refer to **Section 5.1**), they may be more specific than the FDA label. In such cases, the established PA criteria will take precedence over the FDA label. If no specific PA criteria are in place for a covered Cell or Gene Therapy, the FDA label, as outlined above, will be followed.

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) for a beneficiary 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.

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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 the U.S. FDA label 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 or ATC for that therapy, when required by the manufacturer;
d. Repeat treatment in a beneficiary who has received the same or another Cell or Gene Therapy previously, except for therapies that require multiple infusions or doses as part of a single treatment course;
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; and
b. Non-Emergency Medical Transportation (NEMT) for fertility preservation service appointments.

NOTE: Centers for Medicare and Medicaid Services (CMS) shall require participating manufacturers to provide payment for fertility preservation services for a Model Beneficiary who receive therapies administered under the CGT Access Model (**refer to Section 1.1**).

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 on the NC Select Drug List located at https://medicaid.ncdhhs.gov/providers/programs-and-services/prescription-drugs/pharmacy-services. The provider shall obtain prior approval before rendering Cell & Gene Therapies on the NC Select Drug List. Refer to https://www.nctracks.nc.gov/content/public/providers/prior-approval.html ~~https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugs-criteria-new-format.html~~ for a list of Cell & Gene Therapies with established prior approval (PA) criteria. For covered therapies without listed PA criteria, requests should follow the FDA label as specified in **Section 3.2.1**.

Medicaid shall not require prior approval for Cell & Gene Therapies that are not on the NC Select Drug List.

Providers must use the product-specific CPT/HCPCS codes when requesting prior authorization (PA) for Cell and Gene Therapies on the NC Select Drug List, regardless of whether the administration will occur in an inpatient or outpatient hospital setting. 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). The CPT/HCPCS codes included on the PA will be cross walked to ICD-10 PCS codes on inpatient claims.

Continued therapy is not authorized, as most Cell & Gene Therapies~~y~~ ~~is~~ are designed to be administered as a one-time, lifetime treatment, though some therapies may require multiple infusions or doses as part of a single treatment course.

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

For Cell & Gene Therapies (CGTs) that are on the NC Select Drug List, located at https://medicaid.ncdhhs.gov/providers/pharmacy-services, and reimbursed using the NC Select Drug reimbursement methodology, the ~~Cell & Gene~~ drug charges submitted for the therapy must be from a manufacturer enrolled in the Medicaid Drug Rebate Program as described in 42 U.S.C. § 1396r–8 and 42 C.F.R. § 447.509. These CGTs are reimbursed under the methodology outlined in State Plan Attachments 4.19-A and 4.19-B.

For covered CGTs that are not on the NC Select Drug List and are reimbursed under a DRG that bundles the cost of the therapy into the facility payment, the MDRP participation requirement does not apply. These products may be covered when medically necessary, and reimbursement is limited to the applicable DRG rate. No separate, invoice-based reimbursement for the cost of the therapy will be made in these cases.

6.2 Provider Certifications

a. Certain Cell & Gene Therapies, as required by the manufacturer, are exclusively offered at Qualified Treatment Centers (QTC) or Authorized Treatment Centers (ATC). Each QTC or ATC 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 the minimum Transformed Medicaid Statistical Information System (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; 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).

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7.2 Cell & Gene Therapy (CGT) Access Model Requirements

a. A provider submitting a claim for a **Model Beneficiary** (refer to **Section 1.1**) who was administered a **State-Selected Model Drug** (refer to **Section 1.1**) must be registered with the **CMS-designated patient registry** (refer to **Section 1.1**) for the Model and must also seek beneficiary consent for participation in a CMS-specified study.

c. A provider submitting a claim for a **State-Selected Model Drug** must follow the state's specified billing instructions (refer to **Attachment A).**

b. Payment is contingent upon continued compliance with these Model requirements.

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8.0 Policy Implementation and History

Original Effective Date: January 1, 2025

History:

Date	Section or Subsection Amended	Change
01/01/2025	All Sections and Attachment(s)	New Clinical Coverage Policy for U.S. FDA approved Cell & Gene Therapies.
04/01/2025	All Sections and Attachment(s)	Added references to CCPs: • 11A-14 Placental and Umbilical Cord Blood as a Source of Stem Cells • 11A-17 CAR T-Cell Therapy • 11B-3 Islet Cell Transplantation • 11B-9 Thymus Tissue Implantation There are some things on the US FDA Approved Cell & Gene Therapy website (https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products) that would actually fall under these policies.
04/01/2025	Section 1.1	Added definitions for: • Candidate Beneficiary • CMS-Designated Patient Registry • Model Beneficiary • Model Drug • Qualified Treatment Center (QTC) or Authorized Treatment Center (ATC) • Sickle Cell Disease (SCD) • Supplemental Rebate Agreement (SRA) • Value-Based Purchasing (VBP). Specified that our State Selected Model Drugs are LYFGENIA and CASGEVY.
04/01/2025	Section 3.2.1	Added note that if prior approval (PA) criteria have been established for a Cell or Gene Therapy (refer to **Section 5.1**), they may be more specific than the FDA label. In such cases, the established PA criteria will take precedence over the FDA label. If no specific PA criteria are in place for a covered Cell or Gene Therapy, the FDA label, as outlined in Section 3.2.1, will be followed.
04/01/2025	Section 3.2.1	Updated the Qualified Treatment Center (QTC) language to also include Authorized Treatment Center (ATC), as both terms have the same meaning, though manufacturers may use different terminology. Updated language to state FDA label vs. FDA guidelines. Clarified that administration at a Qualified/Authorized Treatment Center is a manufacturer specific requirement.

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Date	Section or Subsection Amended	Change
04/01/2025	Section 4.2.1	Updated the Qualified Treatment Center (QTC) language to also include Authorized Treatment Center (ATC), as both terms have the same meaning, though manufacturers may use different terminology. Updated language to state FDA label vs. FDA guidelines. Clarified that administration at a Qualified/Authorized Treatment Center is a manufacturer specific requirement. Clarified that repeat treatments being non-covered does not apply to therapies that require multiple infusions/doses as part of a single treatment.
04/01/2025	Section 4.2.2	Added the word "Model" before "Beneficiary."
04/01/2025	Section 5.1	Clarified that PA requests for covered CGTs that do not have PA criteria posted on the NCTracks website, should defer to the FDA label. Clarified that J3590 should be used to request PA if a product-specific code has not been assigned. Clarified that while continued therapy is not authorized, as Cell & Gene Therapy is designed to be administered as a one-time, lifetime treatment, some therapies may require multiple infusions or doses as part of a single treatment course.
04/01/2025	Section 6.1	Added reference to 42 U.S.C. § 1396r–8 and 42 C.F.R. § 447.509.
04/01/2025	Section 6.2	Updated the Qualified Treatment Center (QTC) language to also include Authorized Treatment Center (ATC), as both terms have the same meaning, though manufacturers may use different terminology. Clarified that only certain CGT manufacturers impose the Qualified/Authorized Treatment Center requirement. Spelled out Transformed Medicaid Statistical Information System.
04/01/2025	Section 7.2	Clarified CGT Access Model requirements for providers by referring to the new definitions in Section 1.1.
04/01/2025	Attachment A, Section B	Added ICD-10-PCS.
04/01/2025	Attachment A, Section C	Added HCPCS. Removed NDCs.
04/01/2025	Attachment A, Section H	Updated terminology from “Revenue” to “Ratio.” Added reference to 42 CFR § 447.502. Added a note that only Cell & Gene Therapies on the NC Select Drug List, located at https://medicaid.ncdhhs.gov/providers/pharmacy-services are subject to the above reimbursement methodology. All other covered Cell & Gene Therapies shall follow standard payment methodology.

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Date	Section or Subsection Amended	Change
	Section 5.1	Clarified that PA is only required for CGTs on the NC Select Drug List located at https://medicaid.ncdhhs.gov/providers/programs-and-services/prescription-drugs/pharmacy-services. Updated PA link to https://www.nctracks.nc.gov/content/public/providers/prior-approval.html.
	Section 6.1	Added language to clarify that the MDRP requirement only applies to CGTs on the NC Select Drug List.
	Attachment A, Section B	Updated to state: Provider(s) shall attach the invoice for purchase of the Cell & Gene Therapy drug. Clarified these instructions only apply to CGTs on the NC Select Drug List. ICD-10-PCS updated.
	Attachment A, Section C	Added HCPCS. Added revenue code guidance for outpatient claims. Updated to state: Provider(s) shall attach the invoice for purchase of the Cell & Gene Therapy drug. Clarified these instructions only apply to CGTs on the NC Select Drug List.
	Attachment A, Section H	Added language to clarify this logic only applies to CGTs on the NC Select Drug List.

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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 Therap~~y~~ies on the NC Select Drug List 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 and NDC on the claim.
c. Provider(s) shall attach the invoice ~~from manufacturer~~ for purchase of the Cell & Gene Therapy drug.

ICD-10 PCS Code(s)	
XW0Q316	Introduction of Eladocagene exuparvovec into Cranial Cavity and Brain, Percutaneous Approach, New Technology Group 6
XW133H9	Transfusion of Lovotibeglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 9
XW143H9	Transfusion of Lovotibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 9
XW133J8	Transfusion of Exagamglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143J8	Transfusion of Exagamglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
XW133G8	Transfusion of Atidarsagene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8

XW143G8	Transfusion of Atidarsagene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
XW133B8	Transfusion of Betibeglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143B8	Transfusion of Betibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8

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	Unclassified biologics
J3387	Injection, elivaldogene autotemcel, per treatment
J3391	Injection, atidarsagene autotemcel, per treatment
J3392	Injection, exagamglogene autotemcel, per treatment
J3393	Injection, betibeglogene autotemcel, per treatment
J3394	Injection, lovotibeglogene autotemcel, per treatment
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
J1412	Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 1013 vector genomes
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose
J3405	Injection, onasemnogene abeparvovec-brve, per treatment

a. Provider(s) shall file outpatient claims for Cell & Gene Therap~~y~~ies on the NC Select Drug List with revenue code 0891 or 0892 and ~~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 and NDC on the claim.
c. Provider(s) shall attach the invoice ~~from manufacturer~~ for purchase of the Cell & Gene Therapy drug.

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 and other appropriate inpatient services related to the administration of Cell & Gene Therapies on the NC Select Drug List 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 shall be included on the claim.
2. The Actual Acquisition Cost (AAC), as defined in 42 CFR § 447.502, of the drug shall be submitted on the inpatient claim, with the corresponding HCPCS code and NDC. An invoice must be attached to the claim to support the drug cost. The AAC submitted on the claim line must equal the drug cost on the invoice. The drug will be reimbursed at the attached invoice price, with no markup.
3. Refer to the NC Select Drug List Reimbursement Methodology in Attachment 4.19-A of the State Plan located at: https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices.

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

1. In accordance with the State Plan, the outpatient stay and other appropriate outpatient services related to the administration of Cell & Gene Therapies on the NC Select Drug List will be reimbursed using the existing Ratio Cost to Charge (RCC) Outpatient payment methodology. The PA number shall be included on the claim.
2. The Actual Acquisition Cost (AAC), as defined in 42 CFR § 447.502, of the drug shall be submitted on the outpatient claim, with the corresponding HCPCS code and NDC. An invoice must be attached to the claim to support the drug cost. The AAC submitted on the claim line must equal the drug cost on the invoice. The drug will be reimbursed at the lesser of the Average Sales Price (ASP) (if available) or the attached invoice price, with no markup.
3. Refer to the NC Select Drug List Reimbursement Methodology in Attachment 4.19-B, Section 2, and Attachment 4.19-B, Section 12 of the State Plan, located at https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices.

Note: Only Cell & Gene Therapies on the NC Select Drug List, located at https://medicaid.ncdhhs.gov/providers/pharmacy-services are subject to the above reimbursement methodology. All other covered Cell & Gene Therapies shall follow standard payment methodology.