Clinical Policy: Cell and Gene Therapies

Reference Number: WNC.CP.299 Coding Implications
Last Review Date: Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1] **-** This policy discusses medical necessity criteria for Cell & Gene Therapies.

- Human gene therapy aims to manipulate gene expression or alter cellular properties for therapeutic purposes.
- Gene therapy involves modifying a member'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, 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).

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover Cell & Gene Therapies when the member 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 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 Background II), 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.*

II. Medically necessary transportation

A. In addition to the specific criteria covered in Criteria I above, WellCare of North Carolina® may cover Medically Necessary transportation for medical appointments under WellCare of North Carolina® Non-Emergency Medical Transportation benefit. Please refer to Clinical Coverage Policy WNC.CP.262 "Non-Emergency Medical Transportation," available at WellCare NC Clinical Coverage Guidelines for prior authorization information.

B. Medicaid Transportation information, for WellCare of North Carolina members, is available at WellCare NC Medicaid Transportation Services.

III. WellCare of North Carolina® 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 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 members who have 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 member's psychosocial history limits the member's ability to comply with pre- and post-infusion medical care; or

F. When there is current member or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

IV. In addition to the specific criteria not covered above, WellCare of North Carolina® 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) shall require participating manufacturers to provide payment for fertility preservation services for a Model Member who receive therapies administered under the CGT Access Model (refer to Background I. Definitions).*

Background[1]

I. Definitions

A. 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.

B. Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access Model moved from below

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.

C. 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.

D. Fertility Preservation Services

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

E. Medical Noncompliance

Medical noncompliance, also known as nonadherence, refers to a member'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.

F. 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.

G. 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.

H. Psychosocial History
A psychosocial history assessment is a detailed and comprehensive evaluation of a member'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 member 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.

I. 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.

J. 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.

K. 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).**

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

M. 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.

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

II. Prior Approval

A. WellCare of North Carolina shall require prior approval for Cell & Gene Therapies.

B. The provider shall obtain prior approval before rendering Cell & Gene Therapies. Refer to NCTracks Prior Approval Drugs and Criteria..

C. For covered therapies without listed PA criteria, requests should follow the FDA label as specified in Criteria I, above.

D. Providers must use the product-specific CPT/HCPCS codes when requesting prior authorization (PA) for Cell and Gene Therapies, 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.

E. Continued therapy is not authorized, as Cell & Gene Therapy is 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.

III. Provider Qualifications and Occupational Licensing Entity Regulations

A. The Cell & Gene 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.

IV. Provider Certifications

A. 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.

V. Cell & Gene Therapy (CGT) Access Model Requirements

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

B. A provider submitting a claim for a **State-Selected Model Drug** must follow the state's specified billing instructions (Refer to State of North Carolina Medicaid Clinical Coverage Policy No:1S-13 Cell and Gene Therapies, Attachment A. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov).

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

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

ICD-10-PCS Codes	Description
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

ICD-10-PCS Codes	Description
XW143B8	Transfusion of Betibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8

HCPCS Code	Description
J3590	Unclassified biologics
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
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

NOTE:

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

Reimbursement:

I. Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov//

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

A. In accordance with the State Plan, the inpatient stay and other appropriate inpatient services related to the administration of 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 shall be included on the claim.

B. 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.

C. 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-planpublic-notices.

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

A. In accordance with the State Plan, the outpatient stay and other appropriate outpatient services related to the administration of Cell & Gene Therapies will be reimbursed using the existing Ratio Cost to Charge (RCC) Outpatient payment methodology. The PA number shall be included on the claim.

B. 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.

C. 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.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	11/24	11/24
Under Description change 'such as' to 'including' and removed 'furthermore' from last statement. Note below Criteria IV. Changed "a cell and gene therapy," to "therapies administered under the CGT Access Model (refer to Background I. Definitions)." Added Background I.E & I.F. Background II., added "Providers must use the product-specific CPT/HCPCS codes when requesting prior authorization (PA) for Cell and Gene Therapies, regardless of whether the administration will occur in an inpatient or outpatient hospital setting. 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 Cell & Gene Therapy is designed to be administered as a one-time, lifetime treatment." Background Criteria V. added. "Cell & Gene Therapy (CGT) Access Model Requirements." ICD-10 code table, added 'XW133J8 and XW143J8'. HCPCS codes added 'J3392 J3394.' NDC codes added, '73554111101, 51167029001, 51167029009.' Added "and NDC" to Note listed under NDC table.	01/2025	01/2025
Annual Review. Under Criteria I.C. added 'Note: If prior approval (PA) criteria have been established for a Cell or Gene Therapy (refer to Background II), 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		

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Therapy, the FDA label, as outlined above, will be followed.' Criteria I. and Criteria III. 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. Criteria III.D. Clarified that repeat treatments being noncovered does not apply to therapies that require multiple infusions/doses as part of a single treatment. Under Criteria IV. Note - added the word "Model" before "Member." Background I.A,C,F,G,I,J,L,N, added definitions. Background I.K. Added text "State model drug/VBP/SRA and specified that our State Selected Model Drugs are LYFGENIA and CASGEVY. Background II.C. Clarified that PA requests for covered CGTs that do not have PA criteria posted on the NCTracks website, should defer to the FDA label. Background II.D. Clarified that J3590 should be used to request PA if a product-specific code has not been assigned. Background II.E. 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. Background III. Added reference to 42 U.S.C. § 1396r–8 and 42 C.F.R. § 447.509. Background IV.A. 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. Background IV.B. Spelled out Transformed Medicaid Statistical Information System and deleted text "participation requirements for Medicaid and be enrolled in North Carolina Medicaid to be reimbursed for Cell and Gene Therapies.'Background V. Clarified CGT Access Model requirements for providers by referring to the new definitions in Background I. ICD-10 codes added XW133G8 XW143G8 XW133B8 XW143B8. HCPCS codes added J3393 J3398 J3399 J1411 J1413.Deleted NCD table. Beneath HCPCS table, added Reimbursement text for Inpatient & Outpatient Hospital services and NC Medicaid pharmacy link. Under NC Guidance/Claims related information, updated state web address.		

References

1. State of North Carolina Medicaid Clinical Coverage Policy No:1S-13 Cell and Gene Therapies. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published April 1, 2025. Accessed April 3, 2025.

North Carolina Guidance

Eligibility Requirements

1. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise).
2. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
3. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- 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:

I. that is unsafe, ineffective, or experimental or investigational.
II. 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.

EPSDT and Prior Approval Requirements

- 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.
- **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/

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:

i. meet Medicaid qualifications for participation.
ii. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
iii. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

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).

Claims-Related Information
Provider(s) shall comply with the NC Tracks 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:

- Claim Type - as applicable to the service provided:
  Professional (CMS-1500/837P transaction)
  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.
- 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.

- 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.
  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.
- Modifiers - Providers shall follow applicable modifier guidelines.
- Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- Co-payments -
  For Medicaid refer to Medicaid State Plan:
  https://medicaid.ncdhhs.gov/meetingsnotices/medicaid-state-plan-public-notices

- Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.