

**Amendment Number 11 (13)**  
**Contract #30-2020-052-DHB-#**

**Behavioral Health and Intellectual/ Developmental Disability Tailored Plan**

**This Amendment** to the Contract #30-2020-052-DHB-# (“Contract”), as subsequently amended, is between the North Carolina Department of Health and Human Services, Division of Health Benefits (Division), and **BH I/DD Tailored Plan Name** (“Contractor” or “BH I/DD Tailored Plan”), each, a Party and collectively, the Parties.

**Background:**

The purpose of this Amendment is to make clarifications, technical corrections and updates related to the following Sections of the Contract:

- I. Section III. Definitions, Contract Term, General Terms and Conditions, Other Provisions and Protections;
- II. Section V. Scope of Services; and
- III. Section VII. Attachments.

**The Parties agree as follows:**

**I. Modifications to Section III. Definitions, Abbreviations, Contract Term, General Terms and Conditions, and Protections**

**Specific subsections are modified as stated herein.**

**a. *Section III. A. Definitions* is revised and restated to add the following:**

- 276. **Cell and Gene Therapy Access Model Beneficiary:** A Cell and Gene Therapy Access Model Candidate Beneficiary who meets all of the following criteria:
  - a. Has received an infusion of a State-Selected Model Drug;
  - b. Has North Carolina Medicaid as the Beneficiary’s primary payer for the infused State-Selected Model Drug;
  - c. On the date the Beneficiary is infused with the State-Selected Model Drug, a value-based payment supplemental rebate agreement between the Department and the manufacturer of the infused State-Selected Model Drug is in effect; and
  - d. If the Beneficiary is enrolled in a Prepaid Health Plan (including a BH I/DD Tailored Plan) or NC Medicaid Direct on the date the Beneficiary is infused with the State-Selected Model Drug, such population is included in the terms of the value-based payment supplemental rebate agreement between the manufacturer of the infused State-Selected Model Drug and the Department on such infusion date.
- 277. **Cell and Gene Therapy Access Model Candidate Beneficiary:** A Beneficiary who meets all of the following criteria:
  - a. Has a documented medical diagnosis of sickle cell disease; and
  - b. Has North Carolina Medicaid, including through a Prepaid Health Plan or NC Medicaid Direct, as the CGT Beneficiary’s primary payer for a State-Selected Model Drug.
- 278. **Model Drug:** 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.

279. **State-Selected Model Drug:** In the context of the Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access Model, a State-Selected Model Drug 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 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 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).

b. **Section III. B. Abbreviations and Acronyms** is revised and restated to add the following:

264. CGT: Cell and Gene Therapy

265. SCD: Sickle Cell Disease

## II. **Modifications to Section V. Scope of Services**

Specific subsections are modified as stated herein.

a. **Section V. B. Medicaid, 2. Benefits, Second Revised and Restated Table 6: Required Clinical Coverage Policies** is revised and restated in its entirety as follows:

<b>Section V.B. Third Revised and Restated Table 6: Required Clinical Coverage Policies</b>	
<b>Service</b>	<b>Scope</b>
<b>BH and I/DD Services:</b> For these policies, BH I/DD Tailored Plans shall have the flexibility to be less restrictive with regard to Prior Authorization requirements.	
Medicaid State Plan BH Services	Row Reserved
Medicaid State Plan I/DD Services	Row Reserved
1915(c) Home and Community-Based Services (HCBS) Waivers	8P: North Carolina Innovations
<b>Other Services</b>	
Auditory Implant External Parts	13A: Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair 13B: Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair
Obstetrics and Gynecology	1E-7: Family Planning Services
Physician Services	1A-4: Cochlear and Auditory Brainstem Implants 1A-23: Physician Fluoride Varnish Services 1A-36: Implantable Bone Conduction Hearing Aids (BAHA) 1A-39: Routine Costs in Clinical Trial Services for Life Threatening Conditions

<b>Section V.B. Third Revised and Restated Table 6: Required Clinical Coverage Policies</b>	
<b>Service</b>	<b>Scope</b>
Pharmacy	As defined in Section V.B.2.iii. Pharmacy Benefits
Cell and Gene Therapies	1S-13: Cell and Gene Therapies

**b. Section V. B. Medicaid, 2. Benefits, i. Physical Health, Behavioral Health, I/DD, and TBI Benefits Package is revised and restated to add the following:**

(xiv) Cell and Gene Therapies (CGTs)

(a) CGTs and Department Clinical Coverage Policies

- i. The Department has outlined coverage requirements for CGTs approved by the U.S. Food and Drug Administration (FDA) across multiple NC Medicaid Direct Clinical Coverage Policies. To support the BH I/DD Tailored Plan with aligning FDA-approved CGTs to the corresponding NC Medicaid Direct Clinical Coverage Policy, the Department will publish an “Analysis of FDA Approved CGTs for Plan” guidance document for the PHP.
  - a) The BH I/DD Tailored Plan can find all FDA-approved CGT products at: <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.
- ii. The BH I/DD Tailored Plan shall use the “Analysis of FDA Approved CGTs for Plan” guidance document provided by the Department to clarify which NC Medicaid Direct Clinical Coverage Policy covers drugs listed on FDA-approved CGT product lists.
  - a) At a minimum, the “Analysis of FDA Approved CGTs for Plan” guidance document will include information on the product and trade name, whether the drug is in the Medicaid Drug Rebate Program, product type, applicable NC Medicaid Direct Clinical Coverage Policy, and whether the drug is on the NC Select Drug List.
  - b) Minimally, on a calendar quarter basis, the Department will publish an updated version of the “Analysis of FDA Approved CGTs for Plan” guidance document and provide the updated version to the BH I/DD Tailored Plan.

(b) Cell and Gene Therapy (CGT) Access Model

- i. The CGT Access Model is a treatment model wherein CMS facilitates the negotiation, implementation, and evaluation of outcomes-based agreements for cell and gene therapies on behalf of state Medicaid agencies to improve Beneficiary access to innovative treatment and health outcomes and reduce health care expenditures. At this time, CMS has limited the CGT Access Model to gene therapies approved or licensed by the Food and Drug Administration for the treatment of sickle cell disease (SCD) that are covered outpatient drugs under the Medicaid Drug Rebate Program. The Department has elected to participate in CMS’ CGT Access Model for the NC Medicaid Direct and Medicaid Managed Care Programs.
- ii. The Department has selected the following two (2) drugs appearing on the NC Select Drug List as the State-Selected Model Drugs under the CGT Access Model:
  - a) CASGEVY® (exagamglogene autotemcel); and
  - b) LYFGENIA™ (lovotibeglogene autotemcel).

- iii. The BH I/DD Tailored Plan shall participate in the CGT Access Model effective October 1, 2025.
- iv. The BH I/DD Tailored Plan shall cover the services necessary to determine whether a CGT Access Model Candidate Beneficiary enrolled in the BH I/DD Tailored Plan meets prior authorization criteria for the State-Selected Model Drug(s).
- v. The BH I/DD Tailored Plan shall cover the administration of a State-Selected Model Drug to CGT Access Model Beneficiaries enrolled in the BH I/DD Tailored Plan in accordance with the requirements of this Section and as directed by the Department to ensure compliance with CMS requirements of the CGT Access Model.
- vi. Access Policy for State-Selected Model Drugs
  - a) The Department's Access policy for State-Selected Model Drugs is comprised of:
    - 1) Clinical coverage policy 1S-13: Cell and Gene Therapy; and
    - 2) Applicable clinical coverage criteria established by the Department for each State-Selected Model Drug found here: <https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugs-criteria-new-format.html>.
  - b) The BH I/DD Tailored Plan is required to follow the Department's Access policy, as applicable, for each State-Selected Model Drug.
  - c) The BH I/DD Tailored Plan shall publish the Access policy for the State-Selected Model Drug(s) publicly in a manner that is accessible by providers and Members.
  - d) By no later than September 20, 2025, the BH I/DD Tailored Plan shall submit to the Department documentation that the BH I/DD Tailored Plan has published an Access policy for each State-Selected Model Drug that aligns with the Department's Access policy.
- vii. Reimbursement of State-Selected Model Drugs
  - a) The BH I/DD Tailored Plan shall reimburse State-Selected Model Drugs in accordance with *Section V.B.2.iii.(viii)(b)(10)v. NC Select Drug List*.
  - b) The BH I/DD Tailored Plan shall require a provider submitting a claim for reimbursement of a State-Selected Model Drug to follow the billing guidance outlined in Section 3.12.3. of the Department's Managed Care Billing Guide. If the BH I/DD Tailored Plan develops any additional billing guidance related to State-Selected Model Drugs for providers, the guidance is required to align with Section 3.12.3. of the Department's Managed Care Billing Guide.
    - 1) The BH I/DD Tailored Plan shall publish its billing guidance developed for each State-Selected Model Drug publicly in a manner that is accessible by providers.
    - 2) By no later than September 20, 2025, the BH I/DD Tailored Plan shall submit to the Department a copy of its billing guidance developed for each State-Selected Model Drug that aligns with the Department's Managed Care Billing Guide.
  - c) The BH I/DD Tailored Plan is prohibited from reimbursing a provider for administration of a State-Selected Model Drug if:
    - 1) The provider is not a member of the CMS-designated patient registry for the State-Selected Model Drug and a participant in a CMS-specified study; or

- 2) The provider otherwise fails to meet State-Selected Model Drug requirements for reimbursement.
- viii. Continuity of Care for CGT Access Model Beneficiaries
- a) For CGT Access Model Beneficiaries transitioning into the BH I/DD Tailored Plan from NC Medicaid Direct or from another PHP (including another BH I/DD Tailored Plan), the BH I/DD Tailored Plan must honor existing and active prior authorizations for SCD gene-therapy related care and prescriptions on file with NC Medicaid Direct or approved by the disenrolling PHP until the end of the authorization period to ensure continuity of care.
  - b) The BH I/DD Tailored Plan shall allow a CGT Access Model Beneficiary to continue to have access to and shall cover Medically Necessary services furnished by their same SCD gene therapy provider(s) for at least one (1) year after receiving their gene therapy infusion.
  - c) For a period no less than five (5) years following the date of State-Selected Model Drug infusion, the BH I/DD Tailored Plan shall permit a CGT Access Model Beneficiary who has transitioned from another PHP (including from a BH I/DD Tailored Plan) or from NC Medicaid Direct to have access to, and shall cover Medically Necessary services furnished to the CGT Access Model Beneficiary by, a treatment center qualified to administer State-Selected Model Drugs.
- ix. Access Model Network Requirements
- a) The BH I/DD Tailored Plan shall maintain an adequate network of providers qualified to administer State-Selected Model Drugs for its Members in accordance with this Section.
  - b) The BH I/DD Tailored Plan shall have at least one (1) in-network treatment center qualified to administer each State-Selected Model Drug or the BH I/DD Tailored Plan shall develop a template single case agreement for SCD gene therapy.
    - 1) If the BH I/DD Tailored Plan develops a template single case agreement for administration of a State-selected Model Drug, the template or its accompanying documentation, at a minimum, shall:
      - i) Identify which services are provided in-state and out-of-state (as applicable), taking into account the entire patient care journey including the following services: initial consultation to determine whether the CGT Access Model Candidate Beneficiary is eligible for the State-Selected Model Drug; cell harvesting; chemotherapy and all other preparation required per the FDA label; infusion of the State-Selected Model Drug; ancillary care (e.g., behavioral health services); and return visits for long-term follow-up care;
      - ii) Contain payment terms consistent with *Section V.B.2.iii.(viii)(b)(10)v. NC Select Drug List*; and
      - iii) Include terms that contemplate coverage for the duration of the continuity of care period described in *Section V.B.2.i.(xiv)(h) Continuity of Care for CGT Access Model Beneficiaries*.
    - 2) If the BH I/DD Tailored Plan develops a template single case agreement for the administration of a State-Selected Model Drug, the BH I/DD Tailored Plan

is required to submit the template to the Department for review and approval.

- i) The BH I/DD Tailored Plan may utilize proposed single case agreement templates submitted to the Department for review, prior to approval, with notification to the provider that the single case agreement is subject to amendment based upon Department review and approval.
  - ii) Upon approval by the Department, the BH I/DD Tailored Plan shall update the submitted single case agreement template to reflect all changes requested by the Department as a condition of approval, whether or not the template has been utilized in contracting with a provider. The BH I/DD Tailored Plan shall discontinue use of a previously submitted single case agreement template once an amended version is approved.
- 3) The PHP shall respond to questions and requests from a provider related to its single case agreement within five (5) Business Days of receipt and shall render decisions on single case agreements within timeframes specified in 42 C.F.R. § 438.210(d) for authorization decisions.
- c) The BH I/DD Tailored Plan shall identify a primary and secondary point of contact for providers regarding single case agreements and prior authorization, and make the contact information available to all treatment centers authorized to administer SCD gene therapy by posting the information publicly on its website.
- x. Access Model Maintenance of Records
- a) Notwithstanding *Section III.D.37. RECORDS RETENTION*, the BH I/DD Tailored Plan shall retain all books, files, records, documents, and other information related to CGT Access Model participation until May 31, 2045, or six (6) years from the date of notification by the Department of any termination, dispute, or allegation of fraud or similar fault against the Department, State-Selected Model Drug manufacturer, or other entities performing functions or services related to the CGT Access Model, whichever is later.
  - b) This term shall survive termination or expiration of the Contract or until such time that the records are transferred to the Department.

**c. *Section V. B. Medicaid, 4. Providers, i. Provider Network, (vii) Assurances of Adequate Capacity and Services (42 C.F.R. § 438.207), (a)(1)v. is revised to add the following:***

- h) Describe the BH I/DD Tailored Plan's plan to ensure in or out of network access to a qualified treatment center for Cell and Gene Therapy services.

**III. Modifications to Section VII. Attachments**

**Specific Attachments are modified as stated herein.**

- a. ***Third Revised and Restated Attachment B. Summary of Medicaid Covered Services & Clinical Coverage Policies is revised and restated in its entirety as Fourth Revised and Restated Attachment B. Summary of Medicaid Covered Services & Clinical Coverage Policies and attached to this Amendment.***

**IV. Effective Date**

This Amendment is effective September 15, 2025, unless otherwise explicitly stated herein, subject to approval by CMS.

**V. Other Requirements**

Unless expressly amended herein, all other terms and conditions of the Contract, as previously amended, shall remain in full force and effect.

**Execution:**

By signing below, the Parties execute this Amendment in their official capacities and agree to the amended terms and conditions outlined herein as of the Effective Date.

**Department of Health and Human Services, Division of Health Benefits**

\_\_\_\_\_  
Jay Ludlam, Deputy Secretary  
NC Medicaid

Date: \_\_\_\_\_

**BH I/DD Tailored Plan Name**

\_\_\_\_\_  
**CEO**

Date: \_\_\_\_\_

## Fourth Revised and Restated Attachment B: Summary of Medicaid Covered Services & Clinical Coverage Policies

*Fourth Revised and Restated Attachment B. Table 1: Summary of Medicaid Covered Services & Clinical Coverage Policies* documents the list of Clinical Coverage Policies the Department maintains currently for its NC Medicaid Direct program for Medicaid benefits that will be covered by the BH I/DD Tailored Plans. Full details on the policies are available at: <https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies>.

North Carolina's Medicaid State Plan is available here: <https://medicaid.ncdhhs.gov/document/state-plan-under-title-xix-social-security-act-medical-assistance-program>. The Department reserves the right to update the clinical coverage policies for covered benefits.

Section VII. Fourth Revised and Restated Attachment B. Table 1: Summary of Medicaid Covered Services & Clinical Coverage Policies	
SERVICE	KEY REFERENCES
Allergies	NC Clinical Coverage Policy 1N-1, Allergy Testing NC Clinical Coverage Policy 1N-2, Allergy Immunotherapy
Ambulance Services	42 C.F.R. § 410.40 NC State Plan Att. 3.1- A.1, Page 18 NC Clinical Coverage Policy 15
Anesthesia	North Carolina Medicaid State Plan, Att. 3.1-A, Page 3; App. 8 to Att. 3.1-A, Pages 1-4; NC Clinical Coverage Policy 1L-1, Anesthesia Services NC Clinical Coverage Policy 1L-2, Moderate (Conscious) Sedation, AKA Procedural Sedation and Analgesia (PSA)
Auditory Implant External Parts	NC Clinical Coverage Policy 13-A, Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair NC Clinical Coverage Policy 13B, Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement
Burn Treatment and Skin Substitutes	NC Clinical Coverage Policy 1G-1, Burn Treatment NC Clinical Coverage Policy 1G-2, Skin Substitutes
Cardiac Procedures	NC Clinical Coverage Policy 1R-1, Phase II Outpatient Cardiac Rehabilitation Programs NC Clinical Coverage Policy 1R-4, Electrocardiography, Echocardiography, and Intravascular Ultrasound
Cell and Gene Therapies	NC Clinical Coverage Policy 1S-13: Cell and Gene Therapies
Certified pediatric and family nurse practitioner services	SSA, Title XIX, Section 1905(a)(21) 42 C.F.R. § 440.166 North Carolina Medicaid State Plan, Att. 3.1-A, Page 8a
Chiropractic services	SSA, Title XIX, Section 1905(g) 42 C.F.R. § 440.60 North Carolina Medicaid State Plan, Att. 3.1-A, Page 3; Att. 3.1-A.1, Page 11

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
	NC Clinical Coverage Policy 1-F, Chiropractic Services
Clinic services	SSA, Title XIX, Section 1905(a)(9)  42 C.F.R. § 440.90  North Carolina Medicaid State Plan, Att. 3.1-A, Page 4  NC Clinical Coverage Policy 1D-2, Sexually Transmitted Disease Treatment Provided in Health Departments  NC Clinical Coverage Policy 1D-3, Tuberculosis Control and Treatment Provided in Health Departments
Dietary Evaluation and Counseling and Medical Lactation Services	North Carolina Medicaid State Plan, Att. 3.1-B, Pages 7(b), 7(c)  NC Clinical Coverage Policy 1-I, Dietary Evaluation and counseling and Medical Lactation Services
Durable medical equipment (DME)	North Carolina Medicaid State Plan, Att. 3.1-A, Page 3  NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies  NC Clinical Coverage Policy 5A-2, Respiratory Equipment and Supplies  NC Clinical Coverage Policy 5A-3, Nursing Equipment and Supplies  NC Clinical Coverage Policy 5B, Orthotics & Prosthetics
Early and Periodic Screening, Diagnostic and Treatment Services (EPSDT)	SSA, Title XIX, Section 1905(a)(4)(B)  42 U.S.C. 1396(d)(r)  North Carolina Medicaid State Plan, Att. 3.1-A, Page 2  NC Clinical Coverage EPSDT Policy Instructions  <i>Section V.B.2.ii. Early and Periodic Screening, Diagnostic and Treatment (EPSDT) for Medicaid Members</i>
Family planning services	SSA Title XIX, Section 1905(a)(4)(C)  North Carolina Medicaid State Plan, Att. 3.1-A, Page 2  NC Clinical Coverage Policy 1E-7, Family Planning Services
Federally qualified health center (FQHC) services	SSA, Title XIX, Section 1905(a)(2) (C)  42 C.F.R. § 405.2411  42 C.F.R. § 405.2463 42 C.F.R. § 440.20  North Carolina Medicaid State Plan, Att. 3.1-A, Page 1  NC Clinical Coverage Policy 1D-4, Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
Freestanding birth center services (when licensed or otherwise recognized by the State)	SSA, Title XIX, Section 1905(a)(28)  North Carolina Medicaid State Plan Att. 3.1-A, Page 11
Gynecology	North Carolina Medicaid State Plan, Att. 3.1-B, Page 7(a)  NC Clinical Coverage Policy 1E-1, Hysterectomy  NC Clinical Coverage Policy 1E-2, Therapeutic and Non-therapeutic Abortions
Hearing Aids	North Carolina Medicaid State Plan, Att. 3.1-A.1, Pages 6, 7a; Att. 3.1-B, Page 1  NC Clinical Coverage Policy 7, Hearing Aid Services
HIV case management services	Supplement 1 to Attachment 3.1-A, Part G Page 1  North Carolina Clinical Coverage Policy 12B, Human Immunodeficiency Virus (HIV) Case Management
Home health services	SSA, Title XIX, Section 1905(a)(7)  42 C.F.R. §440.70  North Carolina Medicaid State Plan, Att. 3.1-A Page 3; Att. 3.1-A.I, Pages 13, 13a-13a.4  NC Clinical Coverage Policy 3A
Home infusion therapy	North Carolina Medicaid State Plan Att. 3.1-A.1, Page 13a.3  NC Clinical Coverage Policy 3H-1, Home Infusion Therapy
Hospice services	SSA, Title XIX, Section 1905(a)(18)  42 C.F.R. §418  North Carolina Medicaid State Plan 3.1-A, Page 7  NC Clinical Coverage Policy 3D, Hospice Services
ICF-IID services	42 C.F.R. 440.150  8E: Intermediate Care Facilities for Individuals with Intellectual Disabilities
Innovations waiver services	8P: North Carolina Innovations (*Innovations waiver enrollees only)
Inpatient hospital services	SSA, Title XIX, Section 1905(a)(1)  42 C.F.R. §440.10  North Carolina Medicaid State Plan, Att. 3.1-A, Page 1  North Carolina Medicaid State Plan, Att. 3.1-E  NC Clinical Coverage Policy 2A-1, Acute Inpatient Hospital Services  NC Clinical Coverage Policy 2A-2, Long Term Care Hospital Services

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
	NC Clinical Coverage Policy 2A-3, Out of State Services
Inpatient psychiatric services for individuals under age 21	SSA, Title XIX, Section 1905(a)(16) 42 C.F.R. § 440.160 North Carolina Medicaid State Plan, Att. 3.1-A, Page 7; Att. 3.1-A.1, Page 17 NC Clinical Coverage Policy 8B, Inpatient BH Services
Inpatient substance use services	NC Clinical Coverage Policy 8B, Inpatient BH Services: Medically managed intensive inpatient withdrawal services Medically managed intensive inpatient services
Inpatient and Outpatient BH services	North Carolina Medicaid State Plan Att. 3.1-A.1, Pages 12b, 15-A.1-A.5, 15a-15a.35 NC Clinical Coverage Policy 8A: Enhanced Mental Health and Substance Abuse Services limited to services listed: Mobile Crisis Management Intensive-In-Home Services Multisystemic Therapy Psychosocial Rehabilitation Child and Adolescent Day Treatment Partial Hospitalization Professional Treatment Services in a Facility Based Crisis System Substance Use Comprehensive Outpatient Program Medically Monitored Intensive Inpatient Services (substance abuse medically monitored community residential treatment) Clinically Managed Residential Services (substance abuse non-medical community residential treatment) NC Clinical Coverage Policy 8A-1: Assertive Community Treatment (ACT) Program NC Clinical Coverage Policy 8A-2: Facility-Based Crisis Management for Children and Adolescents NC Clinical Coverage Policy 8A-6: Community Support Team (CST) NC Clinical Coverage Policy 8A-7: Ambulatory Withdrawal Management without Extended On-Site Monitoring (ambulatory detoxification) NC Clinical Coverage Policy 8A-8: Ambulatory Withdrawal Management with Extended On-Site Monitoring NC Clinical Coverage Policy 8A-10: Clinically Managed Residential Withdrawal Services (social setting detoxification) NC Clinical Coverage Policy 8A-11: Medically Monitored Inpatient Withdrawal Services (non-hospital medical detoxification)

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
	<p>North Carolina Clinical Coverage Policy 8D-1: Psychiatric Residential Treatment Facilities for Children under the Age of 21</p> <p>North Carolina Clinical Coverage Policy 8D-2: Residential Treatment Services</p> <p>NC Clinical Coverage Policy 8D-4: Clinically Managed Population-Specific High Intensity Residential Program</p> <p>NC Clinical Coverage Policy 8D-5: Clinically Managed Residential Services (Substance abuse non-medical community residential treatment) <sup>£</sup></p> <p>NC Clinical Coverage Policy 8D-6: Medically Monitored Intensive Inpatient Services <sup>£</sup></p> <p>NC Clinical Coverage Policy 8B: Inpatient BH Services</p> <p>NC Clinical Coverage Policy 8C: Outpatient BH Services Provided by Direct-enrolled Providers</p> <p>NC Clinical Coverage Policy 8F – Researched Based BH Treatment for Autism Spectrum Disorders</p> <p>NC Clinical Coverage Policy 8G – Peer Supports</p> <p>NC Clinical Coverage Policy 8I – Psychological Services in Health Departments and School-Based Health Centers Sponsored by Health Departments to the under-21 Population (BH)</p> <p>NC Clinical Coverage Policy 8A-5: Diagnostic Assessment</p> <p>NC Clinical Coverage Policy 8A-9: Opioid Treatment Program (OTP)</p> <p>NC Clinical Coverage Policy 8A-12: Substance Abuse Intensive Outpatient Program (SAIOP)</p> <p>NC Clinical Coverage Policy 8A-13: Substance Use Comprehensive Outpatient Treatment Program (SACOT)</p>
Laboratory and X-ray services	<p>42 C.F.R. § 410.32</p> <p>42 C.F.R. § 440.30</p> <p>NC Medicaid State Plan, Att. 3.1-A, Page 1; Att. 3.1-A.1, Pages 6a, 7a, 11; Att. 3.1-B, Page 2; Att. 3.1-C</p> <p>NC Clinical Coverage Policy 1S-1, Genotyping and Phenotyping for HIV Drug Resistance Testing</p> <p>NC Clinical Coverage Policy 1S-2, HIV Tropism Assay</p> <p>NC Clinical Coverage Policy 1S-3, Laboratory Services</p> <p>NC Clinical Coverage Policy 1S-4, Genetic Testing</p> <p>NC Clinical Coverage Policy 1S-8, Drug Testing for Opioid Treatment and Controlled Substance Monitoring</p> <p>NC Clinical Coverage Policy 1K-1, Breast Imaging Procedures</p>

<sup>£</sup> Clinical coverage policy is being promulgated with effective date July 1, 2024.

<sup>£</sup> Clinical coverage policy is being promulgated with effective date July 1, 2024.

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
	NC Clinical Coverage Policy 1K-2, Bone Mass Measurement NC Clinical Coverage Policy 1K-6, Radiation Oncology NC Clinical Coverage Policy 1K-7, Prior Approval for Imaging Services
Maternal Support Services	North Carolina Medicaid State Plan, Att. 3.1-B, Pages 7(a), 7(a.1) NC Clinical Coverage Policy 1M-2, Childbirth Education NC Clinical Coverage Policy 1M-3, Health and Behavioral Intervention NC Clinical Coverage Policy 1M-4, Home Visit for Newborn Care and Assessment NC Clinical Coverage Policy 1M-5, Home Visit for Postnatal Assessment and Follow-up Care NC Clinical Coverage Policy 1M-6, Maternal Care Skilled Nurse Home Visit
Non-emergent transportation to medical care	42 C.F.R. § 431.53 42 C.F.R. § 440.170 North Carolina Medicaid State Plan, Att. 3.1-A, Page 9; Att. 3.1.-A.1, Page 18 Non-Emergency Medical Transportation Managed Care Policy
Nursing facility services	SSA, Title XIX, Section 1905(a)(4)(A) 42 C.F.R. §440.40 42 C.F.R. §440.140 42 C.F.R. §440.155 NC Medicaid State Plan, Att. 3.1-A, Pages 2, 9 NC Clinical Coverage Policy 2B-1, Nursing Facility Services NC Clinical Coverage Policy 2B-2, Geropsychiatric Units in Nursing Facilities
Obstetrics	North Carolina Medicaid State Plan, Att. 3.1-B, Page 7(a) NC Clinical Coverage Policy 1E-3, Sterilization Procedures NC Clinical Coverage Policy 1E-4, Fetal Surveillance NC Clinical Coverage Policy 1E-5, Obstetrics NC Clinical Coverage Policy 1E-6, Pregnancy Medical Home
Occupational therapy	42 C.F.R. § 440.110 North Carolina Medicaid State Plan, Att. 3.1-A, Page 3a; Att. 3.1-A.1, Pages 7c, 7c.15, 13e NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies NC Clinical Coverage Policy 10A, Outpatient Specialized Therapies NC Clinical Coverage Policy 10B, Independent Practitioners (IP)

**Section VII. Fourth Revised and Restated Attachment B. Table 1:  
Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
Office Based Opioid Treatment (OBOT)	NC Clinical Coverage Policy 1A-41, Office Based Opioid Treatment: Use of Buprenorphine & Buprenorphine-Naloxone
Ophthalmological Services	NC Clinical Coverage Policy 1T-1, General Ophthalmological Services NC Clinical Coverage Policy 1T-2, Special Ophthalmological Services
Optometry services	SSA, Title XIX, Section 1905(a)(12)  42 C.F.R. § 441.30  NC Medicaid State Plan, Att. 3.1-A, Page 3; Att. 3.1-A.1, Page 10a  G.S. § 108A-70.21(b)(2)  NC Clinical Coverage Policy 6A, Routine Eye Exam and Visual Aids for Recipients Under Age 21
Other diagnostic, screening, preventive and rehabilitative services	SSA, Title XIX, Section 1905(a)(13)  North Carolina Medicaid State Plan, Att. 3.1-A, Page 5
Outpatient hospital services	SSA, Title XIX, Section 1905(a)(2)  42 C.F.R. §440.20  North Carolina Medicaid State Plan, Att. 3.1-A, Page 1
Personal care	SSA, Title XIX, Section 1905(a)(24)  42 C.F.R. § 440.167  North Carolina Medicaid State Plan, Att. 3.1-A, Page 9; Att. 3.1-A.1, Pages 19-29  NC Clinical Coverage Policy 3L, State Plan Personal Care Services (PCS)
Pharmacy – including Prescription drugs and medication management	SSA, Title XIX, Section 1905(a)(12)  42 C.F.R. § 440.120  North Carolina Medicaid State Plan, Att. 3.1-A, Page 5; Att. 3.1-A.1, Page 12(c); Att. 3.1-A.1, Pages 14-14h;  NC Prior Approval Drugs and Criteria  NC Preferred Drug List  NC Beneficiary Management Lock-In Program  NC Clinical Coverage Policy 9, Outpatient Pharmacy Program  NC Clinical Coverage Policy 9A, Over-The- Counter Products  NC Clinical Coverage Policy 9B, Hemophilia Specialty Pharmacy Program  NC Clinical Coverage Policy 9D, Off Label Antipsychotic Safety Monitoring in Beneficiaries Through Age 17  NC Clinical Coverage Policy 9E, Off Label Antipsychotic Safety Monitoring in Beneficiaries 18 and Older

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SERVICE	KEY REFERENCES
	North Carolina Medicaid Pharmacy Newsletters
Physical therapy	SSA, Title XIX, Section 1905(a)(11)  42 C.F.R. § 440.110  North Carolina Medicaid State Plan, Att. 3.1-A, Page 3a; Att. 3.1-A.1, Pages 7c, 7c.15, 13e  ID775NC Clinical Coverage Policy 5A, Durable Medical Equipment  NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies  NC Clinical Coverage Policy 10A, Outpatient Specialized Therapies  NC Clinical Coverage Policy 10B, Independent Practitioners (IP)
Physician services	SSA, Title XIX, Section 1905(a)(5)  42 C.F.R. §440.50  North Carolina Medicaid State Plan, Att. 3.1-A, Page 2a; Att. 3.1-A.I, Page 7h  NC Clinical Coverage Policy 1A-2, Adult Preventive Medicine Annual Health Assessment  NC Clinical Coverage Policy 1A-3, Noninvasive Pulse Oximetry  NC Clinical Coverage Policy 1A-4, Cochlear and Auditory Brainstem Implants  NC Clinical Coverage Policy 1A-5, Case Conference for Sexually Abused Children  NC Clinical Coverage Policy 1A-6, Invasive Electrical Bone Growth Stimulation  NC Clinical Coverage Policy 1A-7, Neonatal and Pediatric Critical and Intensive Care Services  NC Clinical Coverage Policy 1A-8, Hyperbaric Oxygenation Therapy  NC Clinical Coverage Policy 1A-9, Blepharoplasty/Blepharoptosis (Eyelid Repair)  NC Clinical Coverage Policy 1A-11, Extracorporeal Shock Wave Lithotripsy  NC Clinical Coverage Policy 1A-12, Breast Surgeries  NC Clinical Coverage Policy 1A-13, Ocular Photodynamic Therapy  NC Clinical Coverage Policy 1A-14, Surgery for Ambiguous Genitalia  NC Clinical Coverage Policy 1A-15, Surgery for Clinically Severe or Morbid Obesity  NC Clinical Coverage Policy 1A-16, Surgery of the Lingual Frenulum  NC Clinical Coverage Policy 1A-17, Stereotactic Pallidotomy  NC Clinical Coverage Policy 1A-19, Transcranial Doppler Studies  NC Clinical Coverage Policy 1A-20, Sleep Studies and Polysomnography Services  NC Clinical Coverage Policy 1A-21, Endovascular Repair of Aortic Aneurysm  NC Clinical Coverage Policy 1A-22, Medically Necessary Circumcision  NC Clinical Coverage Policy 1A-23, Physician Fluoride Varnish Services

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SERVICE	KEY REFERENCES
	<p>NC Clinical Coverage Policy 1A-24, Diabetes Outpatient Self-Management Education</p> <p>NC Clinical Coverage Policy 1A-25, Spinal Cord Stimulation</p> <p>NC Clinical Coverage Policy 1A-26, Deep Brain Stimulation</p> <p>NC Clinical Coverage Policy 1A-27, Electrodiagnostic Studies</p> <p>NC Clinical Coverage Policy 1A-28, Visual Evoked Potential (VEP)</p> <p>NC Clinical Coverage Policy 1A-30, Spinal Surgeries</p> <p>NC Clinical Coverage Policy 1A-31, Wireless Capsule Endoscopy</p> <p>NC Clinical Coverage Policy 1A-32, Tympanometry and Acoustic Reflex Testing</p> <p>NC Clinical Coverage Policy 1A-33, Vagus Nerve Stimulation for the Treatment of Seizures</p> <p>NC Clinical Coverage Policy 1A-34, End Stage Renal Disease (ESRD) Services</p> <p>NC Clinical Coverage Policy 1A-36, Implantable Bone Conduction Hearing Aids (BAHA)</p> <p>NC Clinical Coverage Policy 1A-38, Special Services: After Hours</p> <p>NC Clinical Coverage Policy 1A-39, Routine Costs in Clinical Trial Services for Life Threatening Conditions</p> <p>NC Clinical Coverage Policy 1A-40, Fecal Microbiota Transplantation</p> <p>NC Clinical Coverage Policy 1A-42, Balloon Ostial Dilation</p> <p>NC Clinical Coverage Policy 1B, Physician's Drug Program</p> <p>NC Clinical Coverage Policy 1-O-5, Rhinoplasty and/or Septorhinoplasty</p>
Podiatry services	<p>SSA, Title XIX, Section 1905(a)(5)</p> <p>42 C.F.R. § 440.60</p> <p>G.S. § 90-202.2</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 2a</p> <p>NC Clinical Coverage Policy 1C-1, Podiatry Services</p> <p>NC Clinical Coverage Policy 1C-2, Medically Necessary Routine Foot Care</p>
Private duty nursing services (PDN)	<p>SSA, Title XIX, Section 1905(a)(8)</p> <p>42 C.F.R. § 440.80</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3a; Att. 3.1-A.1, Page 13b</p> <p>NC Clinical Coverage Policy 3G-1, Private Duty Nursing for Beneficiaries Age 21 and Older</p> <p>NC Clinical Coverage Policy 3G-2, Private Duty Nursing for Beneficiaries Under 21 years of Age</p>
Prosthetics, orthotics and supplies	<p>SSA, Title XIX, Section 1905(a)(12)</p> <p>42 C.F.R. § 440.120</p>

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SERVICE	KEY REFERENCES
	North Carolina Medicaid State Plan, Att. 3.1-A, Page 5; Att. 3.1-A.1, Page 7b NC Clinical Coverage Policy 5B, Orthotics and Prosthetics
Reconstructive Surgery	NC Clinical Coverage Policy 1-O-1, Reconstructive and Cosmetic Surgery NC Clinical Coverage Policy 1-O-2, Craniofacial Surgery NC Clinical Coverage Policy 1-O-3, Keloid Excision and Scar Revision NC Clinical Coverage Policy, 1-O-5: Rhinoplasty and/or Septorhinoplasty
Respiratory care services	SSA, Title XIX, Section 1905(a)(20) SSA, Title XIX, Section 102(e)(9)(A) North Carolina Medicaid State Plan, Att. 3.1-A, Page 8a; Appendix 7 to Att. 3.1-A, Page 2; Att. 3.1-A.1, Page 7c NC Clinical Coverage Policy 5A-2, Respiratory Equipment and Supplies NC Clinical Coverage Policy 10D, Independent Practitioners Respiratory Therapy Services
Rural health clinic services (RHC)	SSA, Title XIX, Section 1905(a)(9) 42 C.F.R. § 405.2411 42 C.F.R. § 405.2463 42 C.F.R. § 440.20 North Carolina Medicaid State Plan, Att. 3.1-A, Page 4; Att. 3.1-A, Page 1 NC Clinical Coverage Policy 1D-4, Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics
Services for individuals age 65 or older in an institution for mental disease (IMD)	SSA, Title XIX, Section 1905(a)(14) 42 C.F.R. § 440.140 North Carolina Medicaid State Plan, Att. 3.1-A, Page 6; Att. 3.1-A.1, Page 15b NC Clinical Coverage Policy 8B, Inpatient BH Services
Speech, hearing and language disorder services	42 C.F.R. § 440.110 North Carolina Medicaid State Plan, Att. 3.1-A.1, Pages 7c, 7c.16, 13e NC Clinical Coverage Policy 10A, Outpatient Specialized Therapies NC Clinical Coverage Policy 10B, Independent Practitioners (IP)
Telehealth, Virtual Patient Communications and Remote Patient Monitoring	42 C.F.R. § 410.78 NC Clinical Coverage Policy 1-H, Telehealth, Virtual Patient Communications and Remote Patient Monitoring
Tobacco cessation counseling for pregnant women	SSA, Title XIX, Section 1905(a)(4)(D) North Carolina Medicaid State Plan, Att. 3.1-A, Page 2
Transplants and Related Services	North Carolina Medicaid State Plan, Page 27, Att. 3.1-E, Pages 1-9

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Summary of Medicaid Covered Services & Clinical Coverage Policies**

SERVICE	KEY REFERENCES
	<p>NC Clinical Coverage Policy 11A-1, Hematopoietic Stem-Cell or Bone Marrow Transplantation for Acute Lymphoblastic Leukemia (ALL)</p> <p>NC Clinical Coverage Policy 11A-2, Hematopoietic Stem-Cell and Bone Marrow Transplant for Acute Myeloid Leukemia</p> <p>NC Clinical Coverage Policy 11A-3, Hematopoietic Stem-Cell and Bone Marrow Transplantation for Chronic Myelogenous Leukemia</p> <p>NC Clinical Coverage Policy 11A-5, Allogeneic Hematopoietic and Bone Marrow Transplant for Generic Diseases and Acquired Anemias</p> <p>NC Clinical Coverage Policy 11A-6, Hematopoietic Stem-Cell and Bone Marrow Transplantation for Genetic Treatment of Germ Cell Tumors</p> <p>NC Clinical Coverage Policy 11A-7, Hematopoietic Stem-Cell and Bone Marrow Transplantation for Hodgkin Lymphoma</p> <p>NC Clinical Coverage Policy 11A-8, Hematopoietic Stem-Cell Transplantation for Multiple Myeloma and Primary Amyloidosis</p> <p>NC Clinical Coverage Policy 11A-9, Allogeneic Stem-Cell and Bone Marrow Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms</p> <p>NC Clinical Coverage Policy 11A-10, Hematopoietic Stem-Cell and Bone Marrow Transplantation for Central Nervous System (CNS) Embryonal Tumors and Ependymoma</p> <p>NC Clinical Coverage Policy 11A-11, Hematopoietic Stem-Cell and Bone Marrow Transplant for Non- Hodgkin's Lymphoma</p> <p>NC Clinical Coverage Policy 11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells</p> <p>NC Clinical Coverage Policy 11A-15, Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood</p> <p>NC Clinical Coverage Policy 11A-16, Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)</p> <p>NC Clinical Coverage Policy 11A-17, CAR-T Cell Therapy</p> <p>NC Clinical Coverage Policy 11B-1, Lung Transplantation</p> <p>NC Clinical Coverage Policy 11B-2, Heart Transplantation</p> <p>NC Clinical Coverage Policy 11B-3, Islet Cell Transplantation</p> <p>NC Clinical Coverage Policy 11B-4, Kidney Transplantation</p> <p>NC Clinical Coverage Policy 11B-5, Liver Transplantation</p> <p>NC Clinical Coverage Policy 11B-6, Heart/Lung Transplantation</p> <p>NC Clinical Coverage Policy 11B-7, Pancreas Transplant</p> <p>NC Clinical Coverage Policy 11B-8, Small Bowel and Small Bowel/Liver and Multivisceral Transplants</p>
Ventricular Assist Device	North Carolina Medicaid State Plan, Att. 3.1-E, Page 2

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SERVICE	KEY REFERENCES
	NC Clinical Coverage Policy 11C, Ventricular Assist Device
Vision Services	<p>North Carolina Medicaid State Plan, Att. 3.1-A, Pages 5-6, Page 10a, Page 15; Att. 3.1-B, Pages 1, 4, and 5</p> <p>NC Clinical Coverage Policy 6A, Routine Eye Exam and Visual Aids for Recipients Under Age 21</p> <p>NC Clinical Coverage Policy 6B, Routine Eye Examination and Visual Aids for Beneficiaries 21 Years of Age and Older</p>
1915(i) Option Services	<p>NC Clinical Coverage Policy 8H-1: Supported Employment for IDD and TBI</p> <p>NC Clinical Coverage Policy 8H-2: Individual Placement and Support (IPS)</p> <p>NC Clinical Coverage Policy 8H-3: Individual and Transitional Support (ITS)</p> <p>NC Clinical Coverage Policy 8H-4: Respite</p> <p>NC Clinical Coverage Policy 8H-5: Community Living and Supports (CLS)</p> <p>NC Clinical Coverage Policy 8H-6: Community Transition</p>