

**Amendment Number 27 (28)**  
**Prepaid Health Plan Services**  
**#30-190029-DHB – PHP Name**

**This Amendment** to the Prepaid Health Plan Services **Contract #30-190029-DHB – PHP Name** (Contract) awarded February 4, 2019, and subsequently amended, is between the North Carolina Department of Health and Human Services, Division of Health Benefits (Division), and **PHP Name** (Contractor), each, a Party and collectively, the Parties.

**Background:**

The purpose of this Amendment is to incorporate new requirements for participation in the Centers for Medicare and Medicaid Services Cell and Gene Therapy Access Model. Changes to the following Sections of the Revised and Restated Request for Proposal #30-190029-DHB are being made:

- I. 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, Contract Term, General Terms and Conditions, Other Provisions and Protections**

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

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

186. **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.
187. **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 as the Beneficiary's primary payer for a State-Selected Model Drug.
188. **Model Drug:** Refers to an FDA-approved gene therapy specifically indicated for the treatment of sickle cell disease. It is a therapy for which the Centers for Medicare and Medicaid Services and the manufacturer have agreed upon key terms through negotiation.

189. **State-Selected Model Drug:** In the context of the 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 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).

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

- 221. CGT: Cell and Gene Therapy
- 222. SCD: Sickle Cell Disease

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

Specific subsections are modified as stated herein.

a. **Section V. C. Benefits and Care Management, Fifth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services** is revised and restated in its entirety as follows:

Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services		
SERVICE	DESCRIPTION	KEY REFERENCES
Inpatient hospital services	<p>Services that –</p> <ul style="list-style-type: none"> <li>Are ordinarily furnished in a hospital for the care and treatment of inpatients;</li> <li>Are furnished under the direction of a physician or dentist; and</li> <li>Are furnished in an institution that - <ul style="list-style-type: none"> <li>(i) Is maintained primarily for the care and treatment of patients with disorders other than mental diseases;</li> <li>(ii) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting;</li> <li>(iii) Meets the requirements for participation in Medicare as a hospital; and</li> <li>(iv) Has in effect a utilization review plan, applicable to all Medicaid patients, that meets the requirements of § 482.30 of this chapter, unless a waiver has been granted by the Secretary.</li> </ul> </li> </ul> <p>Inpatient hospital services include: Swing Bed Hospitals: a hospital or critical access hospital (CAH) participating in Medicare that has</p>	<p>SSA, Title XIX, Section 1905(a)(1)</p> <p>42 C.F.R. § 440.10</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 1 North Carolina Medicaid State Plan, Att. 3.1-E</p> <p>NC Clinical Coverage Policy 2A-1, Acute Inpatient Hospital Services</p> <p>NC Clinical Coverage Policy 2A-2, Long Term Care Hospital Services</p> <p>NC Clinical Coverage Policy 2A-3, Out of State Services</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	<p>Center for Medicare and Medicaid Services (CMS) approval to provide post-hospital skilled nursing facility care and meets the requirements set forth in 42 C.F.R. § 482.66.</p> <p>Critical Access Hospitals: a hospital that is certified to receive cost-based reimbursement from Medicare. CAHs shall be located in rural areas and meet certain criteria. CAHs may have a maximum of 25 beds. CAHs that have swing bed agreements (refer to Subsection 1.1.1, above) may use beds for either inpatient acute care or swing beds in accordance with 42 C.F.R. § 485.620(a).</p> <p>Inpatient Rehabilitation Hospitals: a hospital that serves Medicaid and NCHC beneficiaries who have multiple diagnoses. The CMS admission criteria does not address specific diagnoses, but rather the beneficiary's need for rehabilitation and the ability to benefit from it. Inpatient rehabilitation hospitals shall provide daily access to a rehabilitation physician and 24-hour nursing. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least five (5) days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a seven (7)-consecutive day period, beginning with the date of admission to the IRF. In order for an IRF claim to be considered reasonable and necessary, there must be a reasonable expectation that the patient meets all of the requirements listed in 42 C.F.R. § 485.58.</p> <p>Specialty Hospitals: a hospital that is exclusively engaged in the care and treatment of beneficiaries who: a. have cardiac or orthopedic conditions; b. are receiving a surgical procedure; or c. need any other specialized category of services designated by CMS.</p> <p>Hospitals qualifying as long-term acute care hospitals meet the conditions of participation for long term care hospitals and have an average</p>	

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	<p>Medicare length of stay described in 42 C.F.R. § 412.23(e)(2). Refer to clinical coverage policy 2A-2, Long Term Care Hospital Services.</p> <p>Inpatient hospital services do not include Skilled Nursing Facility and Intermediate Care Facility services furnished by a hospital with a swing-bed approval.</p> <p>Inpatient hospital services which include services furnished under the direction of a dentist are carved out of Medicaid Managed Care and should be billed to the Medicaid Fee-for-Service program.</p>	
Outpatient hospital services	<p>Preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—</p> <ul style="list-style-type: none"> <li>Are furnished to outpatients;</li> <li>Are furnished by or under the direction of a physician or dentist; and</li> <li>Are furnished by an institution that— <ul style="list-style-type: none"> <li>(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and</li> <li>(ii) Meets the requirements for participation in Medicare as a hospital; and</li> </ul> </li> </ul> <p>May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of “outpatient hospital services” those types of items and services that are not generally furnished by most hospitals in the State.</p> <p>Outpatient hospital services which include preventive, diagnostic, therapeutic, rehabilitative, or palliative services furnished by or under the direction of a dentist are carved out of Medicaid Managed Care and should be billed to the Medicaid Fee-for-Service program.</p>	<p>SSA, Title XIX, Section 1905(a)(2) 42 C.F.R. § 440.20</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 1</p>
Early and periodic screening, diagnostic and treatment services (EPSDT)	<p>Any service that is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition identified by screening,” whether or not the service is covered under the North Carolina State Medicaid Plan. The services covered under EPSDT are limited to those within the scope of the category of services listed in the federal law at 42 U.S.C. § 1396d(a) [1905(a) of the Social Security Act].</p>	<p>SSA, Title XIX, Section 1905(a)(4)(B) 42 U.S.C. 1396(d)(r)</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 2 NC Clinical Coverage EPSDT Policy Instructions</p> <p>Section V.C.2.: Early and periodic screening, diagnostic and treatment services (EPSDT) of the Contract</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Nursing facility services	<p>A nursing facility is a medical health facility, or a distinct part of a facility (for example, a hospital enrolled by the North Carolina Medicaid (Medicaid) program as a swing-bed provider of nursing facility services), that is licensed and certified by the Division of Health Service Regulation (DHSR) and enrolled with Medicaid to provide nursing facility level of care services.</p> <p>A nursing facility provides daily licensed nursing care and on-site physician services but does not provide the degree of medical treatment, consultation, or medical support services available in an acute care hospital. Skilled nursing services are those which must be furnished under the direct supervision of licensed nursing personnel and under the general direction of a physician in order to achieve the medically desired results and to assure quality patient care. Note: An Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) is not considered to be a nursing facility.</p>	<p>SSA, Title XIX, Section 1905(a)(4)(A) 42 C.F.R. § 440.40</p> <p>42 C.F.R. § 440.140</p> <p>42 C.F.R. § 440.155</p> <p>NC Medicaid State Plan, Att. 3.1-A, Pages 2, 9</p> <p>NC Clinical Coverage Policy 2B-1, Nursing Facility Services</p> <p>NC Clinical Coverage Policy 2B-2, Geropsychiatric Units in Nursing Facilities</p>
Home health services	<p>Home Health Services include medically necessary skilled nursing services, specialized therapies (physical therapy, speech-language pathology, and occupational therapy), home health aide services, and medical supplies provided to beneficiaries in any setting in which normal life activities take place, other than a hospital, nursing facility, or intermediate care facility for individuals with intellectual disabilities; except for home health services in an intermediate care facility for Individuals with Intellectual Disabilities that are not required to be provided by the facility under subpart I of part 483 or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.</p> <p>Home health services cannot be limited to services furnished to beneficiaries who are homebound in accordance with 42 C.F.R. § 440.70.</p>	<p>SSA, Title XIX, Section 1905(a)(7) 42 C.F.R. § 440.70</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A Page 3; Att. 3.1-A.1, Pages 13, 13a-13a.4</p> <p>NC Clinical Coverage Policy 3A</p>
Physician services	<p>Whether furnished in the office, the beneficiary's home, a hospital, a skilled nursing facility, or elsewhere, means services furnished by a physician—</p> <p style="padding-left: 40px;">Within the scope of practice of medicine or osteopathy as defined by State law; and</p> <p style="padding-left: 40px;">By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.</p>	<p>SSA, Title XIX, Section 1905(a)(5) 42 C.F.R. § 440.50</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 2a; Att. 3.1-A.1, Page 7h</p> <p>NC Clinical Coverage Policy 1A-2, Adult Preventive Medicine Annual Health Assessment</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	<p>All medical services performed must be medically necessary and may not be experimental in nature. Experimental is defined as medical care that is investigatory or an unproven procedure or treatment regimen that does not meet generally accepted standards of medical practice in North Carolina. In evaluating whether a particular service is or is not experimental the agency will consider safety, effectiveness and common acceptance as verified through 1) scientifically validated clinical studies 2) medical literature research and 3) qualified medical experts.</p> <p>Therapeutic abortions are covered only in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by physician, place the woman in danger of death unless an abortion is performed; therapeutic abortions are also covered in cases of rape or incest.</p>	<p>NC Clinical Coverage Policy 1A-3, Noninvasive Pulse Oximetry</p> <p>NC Clinical Coverage Policy 1A-4, Cochlear and Auditory Brainstem Implants</p> <p>NC Clinical Coverage Policy 1A-5, Case Conference for Sexually Abused Children</p> <p>NC Clinical Coverage Policy 1A-6, Invasive Electrical Bone Growth Stimulation</p> <p>NC Clinical Coverage Policy 1A-7, Neonatal and Pediatric Critical and Intensive Care Services</p> <p>NC Clinical Coverage Policy 1A-8, Hyperbaric Oxygenation Therapy</p> <p>NC Clinical Coverage Policy 1A-9, Blepharoplasty/Blepharoptosis (Eyelid Repair)</p> <p>NC Clinical Coverage Policy 1A-11, Extracorporeal Shock Wave Lithotripsy</p> <p>NC Clinical Coverage Policy 1A-12, Breast Surgeries</p> <p>NC Clinical Coverage Policy 1A-13, Ocular Photodynamic Therapy</p> <p>NC Clinical Coverage Policy 1A-14, Surgery for Ambiguous Genitalia</p> <p>NC Clinical Coverage Policy 1A-15, Surgery for Clinically Severe or Morbid Obesity</p> <p>NC Clinical Coverage Policy 1A-16, Surgery of the Lingual Frenulum</p> <p>NC Clinical Coverage Policy 1A-17, Stereotactic Pallidotomy</p> <p>NC Clinical Coverage Policy 1A-19, Transcranial Doppler Studies</p> <p>NC Clinical Coverage Policy 1A-20, Sleep Studies and Polysomnography Services</p> <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,</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
		<p>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 1B-1, Botulinum Toxin Treatment: Type A (Botox) and Type B (Myobloc)</p> <p>NC Clinical Coverage Policy 1B-2, Rituximab (Rituxan)</p> <p>NC Clinical Coverage Policy 1B-3, Intravenous Iron Therapy</p>
Rural health clinic services	<p>The specific health care encounters that constitute a core service include the following face to face encounters:</p> <ul style="list-style-type: none"> <li>a. physician services, and services and supplies incident to such services as would otherwise be covered if furnished by a physician or as incident to a physician's services, including drugs and biologicals that cannot be self-administered;</li> <li>b. services provided by physician assistants and</li> </ul>	<p>SSA, Title XIX, Section 1905(a)(9) 42 C.F.R. § 405.2411</p> <p>42 C.F.R. § 405.2463</p> <p>42 C.F.R. § 440.20</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 4; Att. 3.1-A, Page 1</p> <p>NC Clinical Coverage Policy 1D-1, Refugee Health</p>



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SERVICE	DESCRIPTION	KEY REFERENCES
	<p>incident services supplied;</p> <p>c. nurse practitioners and incident services supplied;</p> <p>d. nurse midwives and incident services supplied;</p> <p>e. clinical psychologists and incident services supplied; and</p> <p>f. clinical social workers and incident services supplied.</p>	<p>Assessments Provided in Health Departments</p> <p>NC Clinical Coverage Policy 1D-2, Sexually Transmitted Disease Treatment Provided in Health Departments</p>
Federally qualified health center services	<p>The specific health care encounters that constitute a core service include the following face to face encounters:</p> <p>a. physician services, and services and supplies incident to such services as would otherwise be covered if furnished by a physician or as incident to a physician's services, including drugs and biologicals that cannot be self-administered;</p> <p>b. services provided by physician assistants and incident services supplied;</p> <p>c. nurse practitioners and incident services supplied;</p> <p>d. nurse midwives and incident services supplied;</p> <p>e. clinical psychologists and incident services supplied; and</p> <p>f. clinical social workers and incident services supplied.</p>	<p>SSA, Title XIX, Section 1905(a)(9) 42 C.F.R. § 405.2411</p> <p>42 C.F.R. § 405.2463</p> <p>42 C.F.R. § 440.20</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 1</p> <p>NC Clinical Coverage Policy 1D-1, Refugee Health Assessments Provided in Health Departments</p> <p>NC Clinical Coverage Policy 1D-2, Sexually Transmitted Disease Treatment Provided in Health Departments</p> <p>NC Clinical Coverage Policy 1D-3, Tuberculosis Control and Treatment Provided in Health Departments</p> <p>NC Clinical Coverage Policy 1D-4, Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics</p>
Telemedicine	<p>The use of two-way real-time interactive audio and video between places of lesser and greater medical or psychiatric capability or expertise to provide and support health care when distance separates participants who are in different geographical locations. A beneficiary is referred by one provider to receive the services of another provider via telemedicine or telepsychiatry.</p>	<p>42 C.F.R. § 410.78</p> <p>NC Clinical Coverage Policy 1-H, Telemedicine and Telepsychiatry</p>
Laboratory and X-ray services	<p>All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.</p>	<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 NC Clinical Coverage Policy 1S-3,</p>



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SERVICE	DESCRIPTION	KEY REFERENCES
		<p>Laboratory Services 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> <p>NC Clinical Coverage Policy 1K-2, Bone Mass Measurement</p> <p>NC Clinical Coverage Policy 1K-6, Radiation Oncology</p> <p>NC Clinical Coverage Policy 1K-7, Prior Approval for Imaging Services</p>
Family planning services	Regular Medicaid Family Planning (Medicaid FP) services include consultation, examination, and treatment prescribed by a physician, nurse midwife, physician assistant, or nurse practitioner, or furnished by or under the physician's supervision, laboratory examinations and tests, and medically approved methods, supplies, and devices to prevent conception.	<p>SSA Title XIX, Section 1905(a)(4)(C)</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 2</p> <p>NC Clinical Coverage Policy 1E-7, Family Planning Services</p>
Certified pediatric and family nurse practitioner services	<p>(a) Requirements for certified pediatric nurse practitioner. The practitioner must be a registered professional nurse who meets the requirements specified in either paragraphs</p> <p>(b)(1) or (b)(2) of this section.</p> <p>If the State specifies qualifications for pediatric nurse practitioners, the practitioner must -</p> <ol style="list-style-type: none"> <li>Be currently licensed to practice in the State as a registered professional nurse; and</li> <li>Meet the State requirements for qualification of pediatric nurse practitioners in the State in which he or she furnishes the services.</li> </ol> <p>If the State does not specify, by specialty, qualifications for pediatric nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must -</p> <ol style="list-style-type: none"> <li>Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and</li> <li>Have a pediatric nurse practice limited to providing primary health care to persons</li> </ol>	<p>SSA, Title XIX, Section 1905(a)(21) 42 C.F.R. § 440.166</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 8a</p>

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SERVICE	DESCRIPTION	KEY REFERENCES
	<p>less than 21 years of age.</p> <p>(c) Requirements for certified family nurse practitioner. The practitioner must be a registered professional nurse who meets the requirements specified in either paragraph (c)(1) or (c)(2) of this section.</p> <p>If the State specifies qualifications for family nurse practitioners, the practitioner must -</p> <ul style="list-style-type: none"> <li>i. Be currently licensed to practice in the State as a registered professional nurse; and</li> <li>ii. Meet the State requirements for qualification of family nurse practitioners in the State in which he or she furnishes the services.</li> </ul> <p>(d) If the State does not specify, by specialty, qualifications for family nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must -</p> <ul style="list-style-type: none"> <li>i. Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and</li> <li>ii. Have a family nurse practice limited to providing primary health care to individuals and families.</li> </ul>	
Freestanding birth center services (when licensed or otherwise recognized by the State)	Free standing Birth Centers can only bill for vaginal delivery. These centers are subject to all rules and limitations as specified in the Ambulatory Surgical Center section of the State Plan.	SSA, Title XIX, Section 1905(a)(28) North Carolina Medicaid State Plan Att. 3.1-A, Page 11
Non-emergent transportation to medical care	Medicaid is required to assure transportation to medical appointments for all eligible individuals who need and request assistance with transportation. Transportation will be available if the recipient receives a Medicaid covered service provided by a qualified Medicaid provider (enrolled as a North Carolina Medicaid provider). Medicaid only pays for the least expensive means suitable to the recipient's needs.	42 C.F.R. § 431.53 42 C.F.R. § 440.170 North Carolina Medicaid State Plan, Att. 3.1 D, NC NEMT Policy

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Ambulance Services	Ambulance services provide medically necessary treatment for NC Medicaid Program beneficiaries. Transport is provided only if the beneficiary's medical condition is such that the use of any other means of transportation is contraindicated. Ambulance services include emergency and non-emergency ambulance transport via ground and air medical ambulance for a Medicaid beneficiary.	42 C.F.R. § 410.40 NC State Plan Att. 3.1-A.1, Page 18 NC Clinical Coverage Policy 15
Tobacco cessation counseling for pregnant women	Counseling and pharmacotherapy for cessation of tobacco use by pregnant women.	SSA, Title XIX, Section 1905(a)(4)(D) North Carolina Medicaid State Plan, Att. 3.1-A, Page 2
Prescription drugs and medication management	The North Carolina Medicaid Pharmacy Program offers a comprehensive prescription drug benefit, ensuring that low-income North Carolinians have access to the medicine they need.	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, Pages 14-14h 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 North Carolina Medicaid Pharmacy Newsletters Section V.C.3. Pharmacy Benefits of the Contract

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Clinic services	<p>Preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:</p> <p>(a) Services furnished at the clinic by or under the direction of a physician or dentist.</p> <p>(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.</p> <p>Clinic services include preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients if furnished at the clinic by or under the direction of a dentist are carved out of Medicaid Managed Care and should be billed to the Medicaid Fee-for-Service program.</p>	<p>SSA, Title XIX, Section 1905(a)(9) 42 C.F.R. § 440.90</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 4</p>
Physical therapy	<p>Services to address the promotion of sensor motor function through enhancement of musculoskeletal status, neurobehavioral organization, perceptual and motor development, cardiopulmonary status, and effective environmental adaptation. It includes evaluation to identify movement dysfunction, obtaining, interpreting and integrating information for program planning and treatment to prevent or compensate for functional problems. These services must be provided by a Physical Therapist as defined in 42 C.F.R. § 440.110 and be licensed pursuant to North Carolina State law or a licensed Physical Therapy Assistant under the supervision of a licensed Physical Therapist.</p>	<p>SSA, Title XIX, Section 1905(a)(11) 42 C.F.R. § 440.110</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3a; Att. 3.1-A.1, Pages 7c, 7c.15, 13e</p> <p>NC Clinical Coverage Policy 5A, Durable Medical Equipment</p> <p>NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies</p> <p>NC Clinical Coverage Policy 10A, Outpatient Specialized Therapies</p> <p>NC Clinical Coverage Policy 10B, Independent Practitioners (IP)</p>
Occupational therapy	<p>Services to address the functional needs of a child related to adaptive development, adaptive behavior and play, and sensory, motor, and postural development to improve the child's functional ability to perform tasks, including identification, assessment, intervention, adaptation of the environment, and selection of assistive and orthotic devices. These services must be provided by an Occupational Therapist as defined in 42 C.F.R. § 440.110 and be licensed pursuant to North Carolina State law or by a licensed Occupational Therapy Assistant under the</p>	<p>42 C.F.R. § 440.110</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3a; Att. 3.1-A.1, Pages 7c, 7c.15, 13e</p> <p>NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies</p> <p>NC Clinical Coverage Policy 10A, Outpatient Specialized Therapies</p> <p>NC Clinical Coverage Policy 10B, Independent</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	supervision of a licensed Occupational Therapist.	Practitioners (IP)
Speech, hearing and language disorder services	Services to identify children with communicative or oropharyngeal disorders and delays in communication skills development, referral for medical or other professional services and the provision of services necessary for their rehabilitation. These services must be provided by a Speech Pathologist as defined in 42 C.F.R. §440.110 and be licensed pursuant to North Carolina State law or, a Speech/Language Pathology Assistant who works under the supervision of an enrolled licensed Speech Pathologist. A Speech/Language Pathology Assistant (SLPA) must hold an Associate's degree in Speech/Language Pathology or a Bachelor's Degree from an accredited institution with specialized coursework in Speech/Language Pathology. A SLPA must also pass a competency test by the North Carolina Board of Examiners for Speech and Language Pathologists and Audiologists.	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)
Limited inpatient and outpatient behavioral health services defined in required clinical coverage policy	There must be a current diagnosis reflecting the need for treatment. All covered services must be medically necessary for meeting specific preventive, diagnostic, therapeutic, and rehabilitative needs of the beneficiary.  Please refer to NC Clinical Coverage Policies and services listed.	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  Partial Hospitalization  Professional Treatment Services in Facility-based Crisis  Medically supervised or alcohol and drug abuse treatment center (ADATC) detoxification crisis stabilization  Substance abuse intensive outpatient program (SAIOP)  Substance abuse comprehensive outpatient treatment program (SACOT)  NC Clinical Coverage Policy 8A-2: Facility- based crisis services for children and adolescents  NC Clinical Coverage Policy 8A-5: Diagnostic assessment  North Carolina Medicaid State Plan Att. 3.1-A.1, Page 15a.12: Ambulatory Withdrawal Management without Extended On-Site

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
		<p>Monitoring</p> <p>North Carolina Medicaid State Plan Att. 3.1-A. 1, Page 15a. 11b: Ambulatory Withdrawal Management with Extended On-Site Monitoring</p> <p>NC Clinical Coverage Policy 8A-9: Opioid Treatment Program</p> <p>North Carolina Medicaid State Plan Att. 3.1-A.1., Page 15a. 12-B: Clinically Managed Residential Withdrawal Services (Social Setting Detox)</p> <p>North Carolina Medicaid State Plan Att. 3.1-A.1., Page 15a.12-A: Medically Monitored Inpatient Withdrawal Management Services (Non-hospital medical detoxification)</p> <p>NC Clinical Coverage Policy 8B: Inpatient behavioral health services</p> <p>NC Clinical Coverage Policy 8C: Outpatient Behavioral Health Services Provided by Direct-enrolled Providers</p> <p>NC Clinical Coverage Policy 8F: Research-based Behavioral Health Treatment</p> <p>NC Clinical Coverage Policy 8G: Peer Support Services</p>
Respiratory care services	Respiratory therapy services as defined in 1902(e)(9)(A) of the Social Security Act when provided by the respiratory therapist licensed under the provisions of the North Carolina Respiratory Care Practice Act.	<p>SSA, Title XIX, Section 1905(a)(28) SSA, Title XIX, Section 102(e)(9)(A)</p> <p>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</p> <p>NC Clinical Coverage Policy 5A-2, Respiratory Equipment and Supplies</p> <p>NC Clinical Coverage Policy 10D, Independent Practitioners Respiratory Therapy Services</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Other diagnostic, screening, preventive and rehabilitative services	<p>(A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force; with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and</p> <p>“(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;</p> <p>(B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;</p> <p>(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level.</p>	<p>SSA, Title XIX, Section 1905(a)(13)</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 5</p>
Podiatry services	<p>Podiatry, as defined by G.S. § 90-202.2, “is the surgical, medical, or mechanical treatment of all ailments of the human foot and ankle, and their related soft tissue structure to the level of the myotendinous junction of the ankle. Excluded from the definition of podiatry is the amputation of the entire foot, the administration of an anesthetic other than a local, and the surgical correction of clubfoot of an infant two years of age or less.”</p>	<p>SSA, Title XIX, Section 1905(a)(5) 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 NC Clinical Coverage Policy 1C-1, Podiatry Services</p> <p>NC Clinical Coverage Policy 1C-2, Medically Necessary Routine Foot Care</p>
Optometry	Medicaid shall cover the following optical services	SSA, Title XIX, Section 1905(a)(12) 42 C.F.R. §



**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
services	<p>when provided by ophthalmologists and optometrists:</p> <ul style="list-style-type: none"> <li>(a) routine eye exams, including the determination of refractive errors;</li> <li>(b) prescribing corrective lenses; and dispensing approved visual aids. Opticians may dispense approved visual aids.</li> </ul>	<p>440.30</p> <p>NC Medicaid State Plan, Att. 3.1-A, Page 3; Att. 3.1- A.1, Page 10a</p> <p>G.S. § 108A-70.21(b)(2)</p> <p>NC Clinical Coverage Policy 6A, Routine Eye Exam and Visual Aids for Recipients Under Age 21</p>
Chiropractic services	<p>Chiropractic services are limited to manual manipulation (use of hands) of the spine to correct a subluxation that has resulted in a musculoskeletal condition for which manipulation is appropriate [42 C.F.R. § 440.60(b); 10A NCAC25P.0403(a)(b) and (c)]. The service must relate to the diagnosis and treatment of a significant health problem in the form of a musculoskeletal condition necessitating manual manipulation.</p> <p>Chiropractic services include only services provided by a chiropractor who is licensed by the State. Chiropractic providers must meet the educational requirements as outlined in 42 C.F.R. § 410.21.</p>	<p>SSA, Title XIX, Section 1905(g) 42 C.F.R. § 440.60</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3; Att. 3.1-A.1, Page 11</p> <p>NC Clinical Coverage Policy 1-F, Chiropractic Services</p>
Private duty nursing services	<p>Medically necessary private duty nursing (PDN) services are provided under the direction of the recipient's physician in accordance with 42 C.F.R. §440.80 and prior approval by the Division of Medical Assistance, or its designee.</p> <p>This service is only approvable based on the need for PDN services in the patient's private residence. An individual with a medical condition that necessitates this service normally is unable to leave the home without being accompanied by a licensed nurse and leaving the home requires considerable and taxing effort. An individual may utilize the approved hours of coverage outside of his/her residence during those hours when the individual's normal life activities take the patient out of the home. The need for nursing care to participate in activities outside of the home is not a basis for authorizing PDN services or expanding the hours needed for PDN services.</p> <p>Medicaid will not reimburse for Personal Care Services, Skilled Nursing Visits, or Home Health Aide Services provided during the same hours of the day as PDN services.</p> <p>Medicaid Payments for PDN are made only to</p>	<p>SSA, Title XIX, Section 1905(a)(8) 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>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	<p>agencies enrolled with the Division of Medical Assistance as providers for the service. An enrolled provider must be a State licensed home care agency within North Carolina that is approved in its license to provide nursing services within the State. PDN services shall be rendered by a licensed registered nurse (RN) or licensed practical nurse (LPN) who is licensed by the North Carolina Board of Nursing and employed by a licensed home care agency.</p> <p>A member of the patient's immediate family (spouse, child, parent, grandparent, grandchild, or sibling, including corresponding step and in-law relationship) or a legally responsible person who maintains their primary residence with the recipient may not be employed by the provider agency to provide PDN services reimbursed by Medicaid.</p>	
Personal care	<p>Personal care services (PCS) include a range of human assistance provided to persons of all ages with disabilities and chronic conditions to enable them to accomplish tasks that they would ordinarily do for themselves if they were not disabled. These PCS are intended to provide person-to-person, hands-on assistance by a PCS direct care worker in the beneficiary's home or residential setting with common activities of daily living (ADLs) that, for this program are eating, dressing, bathing, toileting, and mobility. PCS also include: assistance with instrumental activities of daily living (IADLs), such as light housekeeping tasks, when directly related to the approved ADLs and the assistance is specified in the beneficiary's plan of care.</p> <p>PCS is provided by a direct care worker who is employed by a licensed home care agency, or by a residential facility licensed as an adult care home, family care home, supervised living facility, or combination home, and who meets the qualifications specified on Attachment 3.1-A.1, Pages 23-29, section c.</p> <p>In addition to the specified assistance with ADLs and IADLs, qualified PCS direct care workers may also provide Nurse Aide I and Nurse Aide II tasks as specified on Attachment 3.1-A.1, Pages 23-29, section c., pursuant to the North Carolina Board of Nursing as described in 21 NCAC 36.0403 and as specified in the beneficiary's approved plan of care.</p>	<p>SSA, Title XIX, Section 1905(a)(24) 42 C.F.R. § 440.167</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 9; Att. 3.1-A.1, Pages 19-29</p> <p>NC Clinical Coverage Policy 3L, State Plan Personal Care Services (PCS)</p>

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SERVICE	DESCRIPTION	KEY REFERENCES
Hospice services	<p>The North Carolina Medicaid (Medicaid) hospice benefit is a comprehensive set of services, identified and coordinated by a hospice interdisciplinary group (IDG). The IDG to deliver medical, nursing, social, psychological, emotional and spiritual services to enable physical and emotional comfort and support using a holistic approach to maintain the best quality of life for a terminally ill beneficiary, their family and caregivers. The priority of hospice services is to meet the needs and goals of the hospice beneficiary, family and caregivers with daily activities and to help the terminally ill beneficiary with minimal disruption to normal activities, in their environment that best meets the care and comfort needs of the patient and unit of care.</p> <p>The hospice IDG achieves this by organizing and managing, a comprehensive care plan focused on coordinating care, services and resources to beneficiaries, caregivers, and families' necessary for the palliation and management of the terminal illness and related conditions.</p> <p>Only Medicare-certified and North Carolina licensed hospice agencies are eligible to participate as Medicaid hospice providers through NC Division of Health Service Regulation. Each site providing hospice services must be separately licensed. The North Carolina Medical Care Commission has rulemaking authority for hospice. The statutes that apply to hospice agencies are General Statute 131E-200 through 207 and the licensure rules are under Title 10A of the North Carolina Administrative Code (10A NCAC 13K); (G.S. 131E, Article 9, 175-190) and administrative rules (10A NCAC Subchapter 14C). A Hospice provider must have a contract with a nursing home or hospital if services are provided within those facilities.</p>	<p>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</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Durable medical equipment	<p>Durable Medical Equipment (DME) refers to the following categories of equipment and related supplies for use in a beneficiary's home:</p> <ol style="list-style-type: none"> <li>1. Inexpensive or routinely purchased items</li> <li>2. Capped rental/purchased equipment</li> <li>3. Equipment requiring frequent and substantial servicing</li> <li>4. Oxygen and oxygen equipment</li> <li>5. Related medical supplies</li> <li>6. Service and repair</li> <li>7. Other individually priced items</li> <li>8. Enteral nutrition equipment</li> </ol>	<p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3</p> <p>NC Clinical Coverage Policy 5A-1, Physical Rehabilitation Equipment and Supplies</p> <p>NC Clinical Coverage Policy 5A-2, Respiratory Equipment and Supplies</p> <p>NC Clinical Coverage Policy 5A-3, Nursing Equipment and Supplies</p> <p>NC Clinical Coverage Policy 5B, Orthotics &amp; Prosthetics</p>
Prosthetics, orthotics and supplies	<p>Medically necessary orthotic and prosthetic devices are covered by the Medicaid program when prescribed by a qualified licensed health care practitioner and supplied by a qualified provider. Only items determined to be medically necessary, effective and efficient are covered. A qualified orthotic and prosthetic device provider must be approved by the Division of Medical Assistance. The provider requirements are published in Medicaid Clinical Coverage Policies.</p>	<p>SSA, Title XIX, Section 1905(a)(12) 42 C.F.R. § 440.120</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 5; Att. 3.1-A.1, Page 7b</p> <p>NC Clinical Coverage Policy 5B, Orthotics and Prosthetics</p>
Home infusion therapy	<p>Covers self-administered infusion therapy and enteral supplies provided to a North Carolina Medicaid (Medicaid) beneficiary residing in a private residence or to a Medicaid beneficiary residing in an adult care home. Covered services include the following:</p> <ol style="list-style-type: none"> <li>(a) Total parenteral nutrition (TPN)</li> <li>(b) Enteral nutrition (EN)</li> <li>(c) Intravenous chemotherapy</li> <li>(d) Intravenous antibiotic therapy</li> </ol> <p>Pain management therapy, including subcutaneous, epidural, intrathecal, and intravenous pain management therapy.</p>	<p>North Carolina Medicaid State Plan Att. 3.1-A.1, Page 13a.3</p> <p>NC Clinical Coverage Policy 3H-1, Home Infusion Therapy</p>
Services for individuals age 65 or older in an institution for mental disease (IMD)	<p>Provides hospital treatment in a hospital setting twenty-four (24) hours a day. Supportive nursing and medical care are provided under the supervision of a psychiatrist or a physician. This service is designed to provide continuous treatment for beneficiaries with acute psychiatric or substance use problems. *IMD exclusion is waived for Medicaid beneficiaries receiving treatment for substance use disorders.</p>	<p>SSA, Title XIX, Section 1905(a)(14) 42 C.F.R. § 440.140</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 6; Att. 3.1-A.1, Page 15b</p> <p>NC Clinical Coverage Policy 8B, Inpatient Behavioral Health Services</p>

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
Inpatient psychiatric services for individuals under age 21	Provides hospital treatment in a hospital setting twenty-four (24) hours a day. Supportive nursing and medical care are provided under the supervision of a psychiatrist or a physician. This service is designed to provide continuous treatment for beneficiaries with acute psychiatric or substance use problems.	<p>SSA, Title XIX, Section 1905(a)(16) 42 C.F.R. § 440.160</p> <p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 7; Att. 3.1-A.1, Page 17</p> <p>NC Clinical Coverage Policy 8B, Inpatient Behavioral Health Services</p>
Transplants and Related Services	Provides stem-cell and solid organ transplants. Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone marrow-toxic doses of cytotoxic drugs, with or without whole- body radiation therapy.	<p>North Carolina Medicaid State Plan, Page 27, Att. 3.1- E, Pages 1-9</p> <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</p>

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SERVICE	DESCRIPTION	KEY REFERENCES
		<p>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 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 Multi-visceral Transplants</p>
Ventricular Assist Device	Device surgically attached to one or both intact heart ventricles and used to assist or augment the ability of a damaged or weakened native heart to pump blood.	<p>North Carolina Medicaid State Plan, Att. 3.1-E, Page 2</p> <p>NC Clinical Coverage Policy 11C, Ventricular Assist Device</p>
Allergies	<p>Provides testing for allergies. The term "allergy" indicates an abnormally hypersensitive immune reaction in response to exposure to certain foreign substances. Allergy-producing substances are called "allergens. When an allergic individual comes in contact with an allergen, the immune system mounts a response through the immunoglobulin E ( IgE ) antibody.</p> <p>Allergy immunotherapy (a.k.a., desensitization,</p>	<p>NC Clinical Coverage Policy 1N-1, Allergy Testing</p> <p>NC Clinical Coverage Policy 1N-2, Allergy Immunotherapy</p>

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SERVICE	DESCRIPTION	KEY REFERENCES
	hyposensitization, allergy injection therapy, or "allergy shots"), is an effective treatment for allergic rhinitis, allergic asthma, and Hymenoptera sensitivity.	
Anesthesia	<p>Refers to practice of medicine dealing with, but not limited to:</p> <ul style="list-style-type: none"> <li>(a) The management of procedures for rendering a patient insensible to pain and emotional stress during surgical, obstetrical, and other diagnostic or therapeutic procedures.</li> <li>(b) The evaluation and management of essential physiologic functions under the stress of anesthetic and surgical manipulations.</li> <li>(c) The clinical management of the patient unconscious from whatever cause.</li> <li>(d) The evaluation and management of acute or chronic pain.</li> <li>(e) The management of problems in cardiac and respiratory resuscitation.</li> <li>(f) The application of specific methods of respiratory therapy.</li> </ul> <p>The clinical management of various fluid, electrolyte, and metabolic disturbances.</p>	<p>North Carolina Medicaid State Plan, Att. 3.1-A, Page 3; App. 8 to Att. 3.1-A, Pages 1-4;</p> <p>NC Clinical Coverage Policy 1L-1, Anesthesia Services</p> <p>NC Clinical Coverage Policy 1L-2, Moderate (Conscious) Sedation, AKA Procedural Sedation and Analgesia (PSA)</p>
Auditory Implant External Parts	Replacement and repair of external components of a cochlear or auditory brainstem implant device that are necessary to maintain the device's ability to analyze and code sound, therefore providing an awareness and identification of sounds and facilitating communication for individuals with profound hearing impairment.	<p>NC Clinical Coverage Policy 13-A, Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair</p> <p>NC Clinical Coverage Policy 13B, Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement</p>
Burn Treatment and Skin Substitutes	Provides treatment for burns.	<p>NC Clinical Coverage Policy 1G-1, Burn Treatment</p> <p>NC Clinical Coverage Policy 1G-2, Skin Substitutes</p>
Cardiac Procedures	Provides comprehensive program of medical evaluation designed to recondition the cardiovascular system and restore beneficiaries with cardiovascular heart disease to active and productive lives.	<p>NC Clinical Coverage Policy 1R-1, Phase II Outpatient</p> <p>Cardiac Rehabilitation Programs</p> <p>NC Clinical Coverage Policy 1R-4, Electrocardiography, Echocardiography, and Intravascular Ultrasound</p>



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SERVICE	DESCRIPTION	KEY REFERENCES
Dietary Evaluation and Counseling and Medical Lactation Services	Offers direction and guidance for specific nutrient needs related to a beneficiary's diagnosis and treatment. Individualized care plans provide for disease- related dietary evaluation and counseling. Medical lactation services provide support and counseling, or behavioral interventions to improve breastfeeding outcomes.	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
Hearing Aids	Provides hearing aids, FM systems, hearing aid accessories and supplies, and dispensing fees when there is medical necessity.	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
Maternal Support Services	Provides childbirth, health, and behavioral interventions and home nursing benefits for mothers and newborns.	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
Obstetrics and Gynecology	Provides for obstetrical and gynecological care.	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 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
Ophthalmological Services	General ophthalmologic services Include: a. Intermediate ophthalmological services: an evaluation a new or existing condition complicated	NC Clinical Coverage Policy 1T-1, General Ophthalmological Services NC Clinical Coverage Policy 1T-2, Special

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SERVICE	DESCRIPTION	KEY REFERENCES
	<p>with a new diagnostic or management problem not necessarily relating to the primary diagnosis. This service is used for an acute condition or for a chronic condition which is stable.</p> <p>b. Comprehensive ophthalmological services: a general evaluation of the complete visual system. The comprehensive services constitute a single service entity but do not need to be performed at one session.</p> <p>Special ophthalmological services are special evaluations of part of the visual system, which go beyond the services included under general ophthalmological services or in which special treatment is given.</p>	Ophthalmological Services
Pharmacy Services	Provides offers a comprehensive prescription drug benefit.	<p>North Carolina Medicaid State Plan, Att. 3.1-A.1, Page 12(c), Pages 14-14h</p> <p>NC Clinical Coverage Policy 9, Outpatient Pharmacy Program</p> <p>NC Clinical Coverage Policy 9A, Over-the-Counter-Products</p> <p>NC Clinical Coverage Policy 9B, Hemophilia Specialty Pharmacy Program</p> <p>NC Clinical Coverage Policy 9D, Off Label Antipsychotic Safety Monitoring in Beneficiaries Through Age 17</p> <p>NC Clinical Coverage Policy 9E, Off Label Antipsychotic Safety Monitoring in Beneficiaries 18 and Older</p>
Reconstructive Surgery	Reconstructive surgery is any surgical procedure performed to raise a recipient to his or her optimum functioning level.	<p>NC Clinical Coverage Policy 1-O-1, Reconstructive and Cosmetic Surgery</p> <p>NC Clinical Coverage Policy 1-O-2, Craniofacial Surgery</p> <p>NC Clinical Coverage Policy 1-O-3, Keloid Excision and Scar Revision</p>
Vision Services	Optical services include: routine eye exam, including the determination of refractive errors; refraction only; prescribing corrective lenses; and dispensing approved visual aids.	<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>
Telehealth, Virtual Patient Communications	Telehealth: Telehealth is the use of two-way real-time interactive audio and video to provide and support health care services when participants are in	<p>42 C.F.R. § 410.78</p> <p>NC Clinical Coverage Policy 1-H, Telehealth, Virtual Patient Communications and Remote</p>

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SERVICE	DESCRIPTION	KEY REFERENCES
and Remote Patient Monitoring Services	<p>different physical locations.</p> <p>Virtual Patient Communications: Virtual patient communications is the use of technologies other than video to enable remote evaluation and consultation support between a provider and a patient or a provider and another provider.</p> <p>Covered virtual patient communication services include: telephone conversations (audio only); virtual portal communications (e.g., secure messaging); and store and forward (e.g., transfer of data from beneficiary using a camera or similar device that records (stores) an image that is sent by telecommunication to another site for consultation).</p> <p>Remote Patient Monitoring: Remote Patient Monitoring is the use of digital devices to measure and transmit personal health information from a beneficiary in one location to a provider in a different location. Remote patient monitoring enables providers to collect and analyze information such as vital signs (e.g., blood pressure, heart rate, weight, blood oxygen levels) in order to make treatment recommendations. There are two types of remote patient monitoring: Self-Measured and Reported Monitoring and Remote Physiologic Monitoring.</p> <ol style="list-style-type: none"> <li>Self-Measured and Reported Monitoring: When a patient uses a digital device to measure and record their own vital signs, then transmits the data to a provider for evaluation.</li> <li>Remote Physiologic Monitoring: When a patient's physiologic data is wirelessly synced from a patient's digital device where it can be evaluated immediately or at a later time by a provider.</li> </ol>	Patient Monitoring
Cell and Gene Therapies	<p>Medicaid covers Cell and Gene Therapies for beneficiaries who meet specific criteria. The therapy must:</p> <ul style="list-style-type: none"> <li>Have U.S. Food and Drug Administration (FDA) approval.</li> <li>Meet the definition of a covered outpatient drug as defined in 42 CFR § 447.502.</li> <li>Come from a manufacturer enrolled in the Medicaid Drug Rebate Program.</li> <li>Be administered in accordance with FDA-approved guidelines, including: <ul style="list-style-type: none"> <li>Indications and usage.</li> <li>Dosage and administration.</li> </ul> </li> </ul>	NC Clinical Covery Policy 1S-13, Cell and Gene Therapies

**Sixth Revised and Restated Section V.C. Table 1: Summary of Medicaid Services**

SERVICE	DESCRIPTION	KEY REFERENCES
	<ul style="list-style-type: none"> <li>○ Dosage forms and strengths.</li> <li>○ Warnings and precautions.</li> <li>• Be provided at a Qualified Treatment Center (QTC) or Authorized Treatment Center (ATC) approved for administering the therapy, as applicable</li> <li>• In some cases, the State will publish PA criteria for a specific therapy. In this case, the PA criteria will take precedence over the FDA label.</li> </ul> <p>In addition, Medicaid covers Non-Emergency Medical Transportation (NEMT) to assist beneficiaries with transportation to medical appointments.</p> <p>Medicaid does not cover Cell and Gene Therapies under the following circumstances:</p> <ul style="list-style-type: none"> <li>• The therapy has not received FDA approval.</li> <li>• The therapy is administered outside FDA guidelines, including: <ul style="list-style-type: none"> <li>○ Indications and usage.</li> <li>○ Dosage and administration.</li> <li>○ Dosage forms and strengths.</li> </ul> </li> <li>• The therapy is provided at an unapproved facility.</li> <li>• The beneficiary is receiving repeat treatment with the same or another Cell or Gene Therapy.</li> <li>• Psychosocial or non-compliance issues prevent adherence to pre- and post-infusion medical care.</li> </ul> <p>Additional exclusions include:</p> <ul style="list-style-type: none"> <li>• Fertility preservation services associated with Cell and Gene Therapy administration.</li> <li>• NEMT services for fertility preservation appointments.</li> </ul> <p>While Medicaid does not cover fertility preservation services, the Centers for Medicare and Medicaid Services (CMS) requires participating manufacturers to fund these services for therapies provided under the CGT Access Model.</p>	

- b. **Section V. C. Benefits and Care Management, Second Revised and Restated Section V.C. Table 4: Required Clinical Coverage Policies** is revised and restated in its entirety as follows:

Third Revised and Restated Section V.C. Table 4: Required Clinical Coverage Policies	
CLINICAL SUBJECT	SCOPE
Obstetrics and Gynecology	1E-7: Family Planning Services
Physician	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
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
Pharmacy	As defined in <i>Section V.C.3. Pharmacy Benefits</i>
Cell and Gene Therapies	1S-13: Cell and Gene Therapies

- c. **Section V. C. Benefits and Care Management, 1. Medical and Behavioral Health Benefits Package** is revised to add the following:

p. Cell and Gene Therapies (CGTs)

i. CGTs and Department Clinical Coverage Policies

- a) 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 PHP 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.

1. The PHP 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>.

- b) The PHP 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.

1. 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.
2. 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 PHP.

ii. CGT Access Model

- a) 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.
- b) 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:
  - 1. CASGEVY® (exagamglogene autotemcel); and
  - 2. LYFGENIA™ (lovotibeglogene autotemcel).
- c) The PHP shall participate in the CGT Access Model effective October 1, 2025.
- d) The PHP shall cover the services necessary to determine whether a CGT Access Model Candidate Beneficiary enrolled in the PHP meets prior authorization criteria for the State-Selected Model Drug(s).
- e) The PHP shall cover the administration of a State-Selected Model Drug to CGT Access Model Beneficiaries enrolled in the PHP 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.
- f) Access Policy for State-Selected Model Drugs
  - 1. The Department's Access policy for State-Selected Model Drugs is comprised of:
    - i. Clinical Coverage Policy 1S-13: Cell and Gene Therapy; and
    - ii. 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>.
  - 2. The PHP is required to follow the Department's Access policy, as applicable, for each State-Selected Model Drug.
  - 3. The PHP shall publish the Access policy for the State-Selected Model Drug(s) publicly in a manner that is accessible by providers and Members.
  - 4. By no later than September 20, 2025, the PHP shall submit to the Department documentation that the PHP has published an Access policy for each State-Selected Model Drug that aligns with the Department's Access policy.
- g) Reimbursement of State-Selected Model Drugs
  - 1. The PHP shall reimburse State-Selected Model Drugs in accordance with *Section V.C.3.h.ii.j)5. NC Select Drug List*.
  - 2. The PHP 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 PHP 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.

- i. The PHP shall publish the billing guidance developed for each State-Selected Model Drug(s) publicly in a manner that is accessible by providers.
  - ii. By no later than September 20, 2025, the PHP 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.
3. The PHP is prohibited from reimbursing a provider for administration of a State-Selected Model Drug if:
  - i. 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
  - ii. The provider otherwise fails to meet State-Selected Model Drug requirements for reimbursement.
- h) Continuity of Care for CGT Access Model Beneficiaries
  1. For CGT Access Model Beneficiaries transitioning into the PHP from NC Medicaid Direct or from another PHP (including from a BH I/DD Tailored Plan), the PHP must honor existing and active prior authorizations for sickle cell disease 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.
  2. The PHP shall allow a CGT Access Model Beneficiary to continue to have access to and shall cover medically necessary services furnished by their same sickle cell disease gene therapy providers for at least one (1) year after receiving their gene therapy infusion.
  3. For a period no less than five (5) years following the date of State-Selected Model Drug infusion, the PHP 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 for sickle cell disease gene-therapy related care furnished to the CGT Access Model Beneficiary by, a treatment center qualified to administer State-Selected Model Drugs.
- i) Access Model Network Requirements
  1. The PHP shall maintain an adequate network of providers qualified to administer State-Selected Model Drugs for its Members in accordance with this Section.
  2. The PHP shall have at least one (1) in-network treatment center qualified to administer each State-Selected Model Drug or the PHP shall develop a template single case agreement for sickle cell disease gene therapy.
    - i. If the PHP develops a template single case agreement for administration of a State-selected Model Drug, the template or its accompanying documentation, at a minimum, shall:
      - a) 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 as 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;
  - b) Contain payment terms consistent with *Section V.C.3.h.ii.j)5. NC Select Drug List*; and
  - c) Include terms that contemplate coverage for the duration of the continuity of care period described in *Section V.C.1.p.ii.h) Continuity of Care for CGT Access Model Beneficiaries*.
  - ii. If the PHP develops a template single case agreement for the administration of a State-Selected Model Drug, the PHP is required to submit the template to the Department for review and approval.
    - a) The PHP 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.
    - b) Upon approval by the Department, the PHP shall update 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 PHP shall discontinue use of a previously submitted single case agreement template once an amended version is approved.
  - iii. 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.
  - 3. The PHP shall identify a primary and secondary point of contact for providers regarding single case agreements and prior authorization and shall make the contact information available to all treatment centers authorized to administer sickle cell disease gene therapy by posting the information publicly on its website.
  - j) Access Model Maintenance of Records
    - 1. Notwithstanding *Section III.D.36. RECORD RETENTION*, the PHP 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 faulty against the Department, State-Selected Model Drug manufacturer, or other entities performing functions or services related to the CGT Access Model, whichever is later.
    - 2. This term shall survive termination or expiration of the Contract or until such time that the records are transferred to the Department.
- d. ***Section V. D. Providers, 1. Provider Network, g. Assurances of Adequate Capacity and Services (42 C.F.R. § 438.207), i., a), 3. is revised to add the following:***
- viii. Describe the PHP'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. *Attachment B. First Revised and Restated Clinical Coverage Policy List is revised and restated in its entirety as Attachment B. Second Revised and Restated Clinical Coverage Policy List 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: \_\_\_\_\_

**Plan Name**

\_\_\_\_\_  
**Plan Signature Authority**

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

## Attachment B. Second Revised and Restated Clinical Coverage Policy List

The *Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List* below documents the complete list of Clinical Coverage Policies the Department maintains currently for its Fee-for-Service program. Full detail on the policies is available at: <https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies>.

Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List	
CLINICAL SUBJECT	SCOPE
Allergies	1N-1: Allergy Testing 1N-2: Allergy Immunotherapy
Ambulance Services	15: Ambulance Services
Anesthesia	1L-1: Anesthesia Services 1L-2: Moderate (Conscious) Sedation, AKA Procedural Sedation and Analgesia (PSA)
Burn Treatment and Skin Substitutes	1G-1: Burn Treatment 1G-2: Skin Substitutes
Chiropractic Services	1F: Chiropractic Services
Cardiac	1R-1: Phase II Outpatient Cardiac Rehabilitation Programs 1R-4: Electrocardiography, Echocardiography, and Intravascular Ultrasound
Community Based Services	3A: Home Health Services 3D: Hospice Services 3G-1: Private Duty Nursing for Beneficiaries Age 21 and Older 3G-2: Private Duty Nursing for Beneficiaries Under 21 years of Age 3H-1: Home Infusion Therapy 3L: State Plan Personal Care Services (PCS)
Dietary Evaluation and Counseling and Medical Lactation Services	1-I: Dietary Evaluation and Counseling and Medical Lactation Services
Facility Services	2A-1: Acute Inpatient Hospital Services 2A-2: Long Term Care Hospital Services 2A-3: Out-of-State Services

<b>Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List</b>	
<b>CLINICAL SUBJECT</b>	<b>SCOPE</b>
	2B-2: Geropsychiatric Units in Nursing Facilities
Hearing Aid Services	7: Hearing Aid Services
Laboratory Services	1S-1: Genotyping and Phenotyping for HIV Drug Resistance Testing 1S-2: HIV Tropism Assay 1S-3: Laboratory Services 1S-4: Genetic Testing 1S-8: Drug Testing for Opioid Treatment and Controlled Substance Monitoring
Maternal Support Services (Baby Love)	1M-2: Childbirth Education 1M-3: Health and Behavior Intervention 1M-4: Home Visit for Newborn Care and Assessment 1M-5, Home Visit for Postnatal Assessment and Follow-up Care 1M-6: Maternal Care Skilled Nurse Home Visit
Medical Equipment	5A-1: Physical Rehabilitation Equipment and Supplies 5A-2: Respiratory Equipment and Supplies 5A-3: Nursing Equipment and Supplies 5B: Orthotics & Prosthetics
Obstetrics and Gynecology	1E-1: Hysterectomy 1E-2: Therapeutic and Non-Therapeutic Abortions 1E-3: Sterilization Procedures 1E-4: Fetal Surveillance 1E-5: Obstetrics 1E-6: Pregnancy Medical Home
Ophthalmological Services	1T-1: General Ophthalmological Services 1T-2: Special Ophthalmological Services
Physician	1A-2: Preventive Medicine Annual Health Assessment 1A-3: Noninvasive Pulse Oximetry

Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List	
CLINICAL SUBJECT	SCOPE
	1A-6: Invasive Electrical Bone Growth Stimulation 1A-7: Neonatal and Pediatric Critical and Intensive Care Services 1A-8: Hyperbaric Oxygenation Therapy 1A-9: Blepharoplasty/Blepharoptosis (Eyelid Repair) 1A-11: Extracorporeal Shock Wave Lithotripsy 1A-12: Breast Surgeries 1A-13: Ocular Photodynamic Therapy 1A-14: Surgery for Ambiguous Genitalia 1A-15: Surgery for Clinically Severe or Morbid Obesity 1A-16: Surgery of the Lingual Frenulum 1A-17: Stereotactic Pallidotomy 1A-19: Transcranial Doppler Studies 1A-20: Sleep Studies and Polysomnography Services 1A-21: Endovascular Repair of Aortic Aneurysm 1A-22: Medically Necessary Circumcision 1A-24: Diabetes Outpatient Self-Management Education 1A-25: Spinal Cord Stimulation 1A-26: Deep Brain Stimulation 1A-27: Electrodiagnostic Studies 1A-28: Visual Evoked Potential (VEP) 1A-30: Spinal Surgeries 1A-31: Wireless Capsule Endoscopy 1A-32: Tympanometry and Acoustic Reflex Testing 1A-33: Vagus Nerve Stimulation for the Treatment of Seizures 1A-34: End Stage Renal Disease (ESRD) Services 1A-38: Special Services: After Hours 1A-40: Fecal Microbiota Transplantation 1A-41: Office-Based Opioid Treatment: Use of Buprenorphine and Buprenorphine-Naloxone

Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List	
CLINICAL SUBJECT	SCOPE
	1A-42: Balloon Osital Dilation
Podiatry	1C-1: Podiatry Services 1C-2: Medically Necessary Routine Foot Care
Radiology	1K-1: Breast Imaging 1K-2: Bone Mass Measurement 1K-6: Radiation Oncology 1K-7: Prior Approval for Imaging Services
Reconstructive Surgery	1-O-1: Reconstructive and Cosmetic Surgery 1-O-2: Craniofacial Surgery 1-O-3: Keloid Excision and Scar Revision 1-O-5: Rhinoplasty and/or Septorhinoplasty
Rural Health Clinics, FQHCs and Health Departments	1D-1: Refugee Health Assessments Provided in Health Departments 1D-2: Sexually Transmitted Disease Treatment Provided in Health Departments 1D-3: Tuberculosis Control and Treatment Provided in Health Departments 1D-4: Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics
Solid Organ Transplants	11B-1: Lung Transplantation 11B-2: Heart Transplantation 11B-3: Islet Cell Transplantation 11B-4: Kidney (Renal) Transplantation 11B-5: Liver Transplantation 11B-6: Heart/Lung Transplantation 11B-7: Pancreas Transplant 11B-8: Small Bowel and Small Bowel/Liver and Multivisceral Transplants
Specialized Therapies	10A: Outpatient Specialized Therapies 10B: Independent Practitioners (IP)

Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List	
CLINICAL SUBJECT	SCOPE
	10D: Independent Practitioners Respiratory Therapy Services
Stem Cell or Bone Marrow Transplants	<p>11A-1: Hematopoietic Stem-Cell or Bone Marrow Transplantation for Acute Lymphoblastic Leukemia (ALL)</p> <p>11A-2: Hematopoietic Stem-Cell and Bone Marrow Transplant for Acute Myeloid Leukemia)</p> <p>11A-3: Hematopoietic Stem-Cell &amp; Bone Marrow Transplantation for Chronic Myelogenous Leukemia</p> <p>11A-5: Allogeneic Hematopoietic &amp; Bone Marrow Transplant for Genetic Diseases and Acquired Anemias</p> <p>11A-6: Hematopoietic Stem-Cell &amp; Bone Marrow Transplantation in the Treatment of Germ Cell Tumors</p> <p>11A-7: Hematopoietic Stem-Cell &amp; Bone Marrow Transplantation for Hodgkin Lymphoma</p> <p>11A-8: Hematopoietic Stem-Cell &amp; Bone Marrow Transplantation for Multiple Myeloma and Primary Amyloidosis</p> <p>11A-9: Allogeneic Stem-Cell &amp; Bone Marrow Transplantation for Myelodysplastic Syndromes &amp; Myeloproliferative Neoplasms</p> <p>11A-10: Hematopoietic Stem-Cell &amp; Bone Marrow Transplantation for Central Nervous System (CNS) Embryonal Tumors &amp; Ependymoma</p> <p>11A-11: Hematopoietic Stem-Cell &amp; Bone Marrow Transplant for Non-Hodgkin's Lymphoma</p> <p>11A-14: Placental and Umbilical Cord Blood as a Source of Stem Cells</p> <p>11A-15: Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood</p>
	11A-16: Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Telehealth, Virtual Patient Communications and Remote Patient Monitoring	NC Clinical Coverage Policy 1-H, Telehealth, Virtual Patient Communications and Remote Patient Monitoring



Second Revised and Restated Section VII. Attachment B. Table 1: Clinical Coverage Policy List	
CLINICAL SUBJECT	SCOPE
Ventricular Assist Device	11C: Ventricular Assist Device
Vision Services	6A: Routine Eye Exam and Visual Aids for Recipients Under Age 21
Cell and Gene Therapies	1S-13: Cell and Gene Therapies