

## **Table of Contents**

**State/Territory Name: North Carolina**

**State Plan Amendment (SPA) #: 25-0004**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S3-14-28  
Baltimore, Maryland 21244-1850



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**Financial Management Group**

May 1, 2025

Jay Ludlam  
Office of the Deputy Secretary  
Department of Health and Human Services  
2001 Mail Service Center  
Raleigh, NC 27699-20014

RE: TN NC-25-0004

Dear Secretary Ludlam:

The Centers for Medicare & Medicaid Services (CMS) has reviewed the proposed North Carolina state plan amendment (SPA) to Attachments 4.19-A and 4.19-B NC-25-0004, which was submitted to CMS on February 7, 2025. This plan amendment adds establishes a cost-based reimbursement methodology for NC Select Drugs, including Cell and Gene Therapies administered in the Hospital Inpatient, Hospital Outpatient, and Professional Outpatient settings.

We reviewed your SPA submission for compliance with statutory requirements, including in sections 1902(a)(2), 1902(a)(13), 1902(a)(30), and 1903 as it relates to the identification of an adequate source for the non-federal share of expenditures under the plan, as required by 1902(a)(2) of the Social Security Act and the applicable implementing Federal regulations.

Based upon the information provided by the state, we have approved the amendment with an effective date of January 1, 2025. We are enclosing the approved CMS-179 and a copy of the new state plan pages.

If you have any additional questions or need further assistance, please contact Ysabel Gavino at 667-290-8856 or via email at [Maria.Gavino@cms.hhs.gov](mailto:Maria.Gavino@cms.hhs.gov), or James Francis at 857-357-6378 or via email at [James.Francis@cms.hhs.gov](mailto:James.Francis@cms.hhs.gov).

Sincerely,



Rory Howe  
Director  
Financial Management Group

Enclosures

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL  
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

2 5 — 0 0 0 4

2. STATE

NC

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT



XIX



XXI

TO: CENTER DIRECTOR  
CENTERS FOR MEDICAID & CHIP SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

January 01, 2025

5. FEDERAL STATUTE/REGULATION CITATION

CMS 2345-FC and 42 CFR 447.502.

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 25 \$ 0  
b. FFY 26 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT  
Attachment 4.19-A, Page 9, 4.19-B, Section 2, Page 1c, and  
4.19-B, Section 12, Pages 2a-2b

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable)

Attachment 4.19-A, Page 9, 4.19-B, Section 2, Page 1c,  
~~and 4.19 B, Section 12, Pages 2a-2b~~

9. SUBJECT OF AMENDMENT

NC Select Drugs

10. GOVERNOR'S REVIEW (Check One)



GOVERNOR'S OFFICE REPORTED NO COMMENT



COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

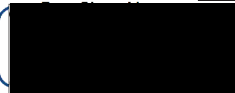


NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL



OTHER, AS SPECIFIED: Secretary

11. SIGNATURE OF STATE AGENCY



12. TYPED NAME  
Jay Ludlam

13. TITLE  
Deputy Secretary

14. DATE SUBMITTED 01/24/25 | 3:28 PM EST

15. RETURN TO

Office of the Deputy Secretary  
Department of Health and Human Services  
2001 Mail Service Center  
Raleigh, NC 27699-20014

**FOR CMS USE ONLY**

16. DATE RECEIVED  
February 7, 2025

17. DATE APPROVED  
May 1, 2025

**PLAN APPROVED - ONE COPY ATTACHED**

18. EFFECTIVE DATE OF APPROVED MATERIAL  
January 1, 2025

19. SIGNATURE OF APPROVING OFFICIAL



20. TYPED NAME OF APPROVING OFFICIAL  
Rory Howe

21. TITLE OF APPROVING OFFICIAL  
Director, Financial Management Group

22. REMARKS

On 4/28/25, North Carolina authorized a pen-and-ink correction to Block 8 to delete "and 4.19-B, Section 12, Pages 2a-2b." (YG)

**State Plan under Title XIX of the Social Security Act  
MEDICAL ASSISTANCE**

**State: NORTH CAROLINA**

**Payments for Remedial Care and Services: Inpatient Hospital**

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**NC SELECT DRUGS REIMBURSEMENT INCLUDING BUT NOT LIMITED TO CELL AND GENE THERAPIES**

Effective January 1, 2025, Inpatient Hospital Physician Administered Select Drugs, as defined by the list of drugs included in the NC Select Drugs List located at the following link, <https://medicaid.ncdhhs.gov/providers/pharmacy-services>, are reimbursable based on the following methodology. Prior authorization is required to receive reimbursement for the administration of the NC Select Drugs and their utilization. Drugs identified on the NC Select Drugs List shall be excluded from DRG reimbursement.

NC Select Drugs Including but Not Limited to Cell and Gene Therapies:

Inpatient Hospitals NC Select Drug reimbursement shall be based on the ingredient component of the select drug, at the Actual Acquisition Cost (AAC) net of all costs such as rebates, received by the hospital, and discounts. NC Select Drugs administered in an Inpatient Hospital setting shall be reimbursed directly to the hospital.

Supplemental charges to cover the administration of the drug shall be reimbursed based on the appropriate DRG. NC Medicaid will not reimburse point of sale pharmacies for the drug, including Specialty Pharmacies, directly for the NC Select Drugs or their administration. The hospital CEO, CFO, or their designated representative responsible for billing shall attest the AAC reflects the actual costs incurred by the hospital for the drug. NC Select Drug reimbursement requires submission of an invoice showing the AAC of the drug.

All drugs on the NC Select Drug List are carved out of 340B. Providers may not utilize 340B inventory for NC Medicaid members for those drugs listed on the NC Select Drug List.

For more information regarding Inpatient Hospital methodology, reference Outpatient Hospital methodology in NC State Plan Attachment 4.19-B, Section 2, and Pharmacy methodology in NC State Plan Attachment 4.19-B, Section 12.

All drugs included on the NC Select Drug List are subject to the special reimbursement methodology defined on this page due to their cost.

State Plan under Title XIX of the Social Security Act  
Medical Assistance Program

State: NORTH CAROLINA

**PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE**

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**NC SELECT DRUGS INCLUDING BUT NOT LIMITED TO CELL AND GENE THERAPIES REIMBURSEMENT**

Effective January 1, 2025, Hospital Outpatient Physician Administered Select Drugs, as defined by the list of drugs included in the NC Select Drugs List located at the following link, <https://medicaid.ncdhhs.gov/providers/pharmacy-services>, are reimbursable based on the following methodology. Prior authorization is required to receive reimbursement for the administration of the NC Select Drugs and their utilization. NC Select Drugs reimbursement shall not be based on the RCC methodology.

NC Select Drugs Including but Not Limited to Cell and Gene Therapies:  
Hospital Outpatient NC Select Drug reimbursement shall be based on the ingredient component of the NC Select Drug at the lesser of the Actual Acquisition Cost (AAC) or the Average Sales Price (ASP) net of all costs such as rebates, received by the hospital, and discounts. NC Select Drugs administered in an Outpatient Hospital setting shall be reimbursed directly to the hospital.

Outpatient supplemental charges to cover the administration of the select drug shall be reimbursed based on the Outpatient Hospital RCC methodology. NC Medicaid will not reimburse point of sale pharmacies, including Specialty Pharmacies, directly for NC Select Drugs or their administration. The hospital CEO, CFO, or their designated representative responsible for billing shall attest the AAC reflects the actual costs incurred by the hospital for the drug.

NC Select Drug reimbursement requires submission of an invoice showing the AAC of the drug. Drugs will be reimbursed at the lesser of the AAC or the ASP. If the ASP is unavailable, reimbursement shall be the AAC.

All drugs on the NC Select Drug List are carved out of 340B. Providers may not utilize 340B inventory for NC Medicaid members for those drugs listed on the NC Select Drug List.

For more information regarding Outpatient Hospital methodology, reference Inpatient Hospital methodology in NC State Plan Attachment 4.19-A, and Pharmacy methodology in NC State Plan Attachment 4.19-B, Section 12.

All drugs included on the NC Select Drug List are subject to the special reimbursement methodology defined on this page due to their cost.

**MEDICAL ASSISTANCE**  
State: **NORTH CAROLINA**

**PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE**

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**NC SELECT DRUGS INCLUDING BUT NOT LIMITED TO CELL AND GENE THERAPIES REIMBURSEMENT**

Inpatient Hospital reimbursement methodology for NC Select Drugs can be found in attachment 4.19-A, Page 9 of the State Plan.

Effective January 1, 2025, Hospital Outpatient Physician Administered Select Drugs, as defined by the list of drugs included in the NC Select Drugs List located at the following link, <https://medicaid.ncdhhs.gov/providers/pharmacy-services>, are reimbursable based on the following methodology. Prior authorization is required to receive reimbursement for the administration of the NC Select Drugs and their utilization. NC Select Drugs reimbursement shall not be based on the RCC methodology.

NC Select Drugs Including but Not Limited to Cell and Gene Therapies:

Hospital Outpatient NC Select Drug reimbursement shall be based on the ingredient component of the NC Select Drug at the lesser of the Actual Acquisition Cost (AAC) or the Average Sales Price (ASP) net of all costs such as rebates, received by the hospital, and discounts. NC Select Drugs administered in an Outpatient Hospital setting shall be reimbursed directly to the hospital.

Outpatient supplemental charges to cover the administration of the select drug shall be reimbursed based on the Outpatient Hospital RCC methodology. NC Medicaid will not reimburse point of sale pharmacies, including Specialty Pharmacies, directly for NC Select Drugs or their administration. The hospital CEO, CFO, or their designated representative responsible for billing shall attest the AAC reflects the actual costs incurred by the hospital for the drug.

NC Select Drug reimbursement requires submission of an invoice showing the AAC of the drug. Drugs will be reimbursed at the lesser of the AAC or the ASP. If the ASP is unavailable, reimbursement shall be the AAC.

All drugs on the NC Select Drug List are carved out of 340B. Providers may not utilize 340B inventory for NC Medicaid members for those drugs listed on the NC Select Drug List.

For more information regarding Outpatient Hospital methodology, reference Inpatient Hospital methodology in NC State Plan Attachment 4.19-A, and Pharmacy methodology in NC State Plan Attachment 4.19-B, Section 12.

All drugs included on the NC Select Drug List are subject to the special reimbursement methodology defined on this page due to their cost.

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**TN No: 25-0004**

**Supersedes**

**TN No: New**

**Approval Date: May 1, 2025**

**Effective Date: 01/01/2025**

**MEDICAL ASSISTANCE**

**STATE: NORTH CAROLINA**

**PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE**

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Effective January 1, 2025, Outpatient Professional Service Setting Physician Administered Select Drugs, as defined by the list of drugs included in the NC Select Drugs List located at the following link, <https://medicaid.ncdhhs.gov/providers/pharmacy-services>, are reimbursable based on the following methodology. Prior authorization is required to receive reimbursement for the administration of the NC Select Drugs and their utilization. NC Select Drugs reimbursement shall not be based on the PADP Fee Schedule.

NC Select Drugs Including but Not Limited to Cell and Gene Therapies:

Outpatient Professional NC Select Drug reimbursement shall be based on the ingredient component of the NC Select Drug at the lesser of the Actual Acquisition Cost (AAC) or the Average Sales Price (ASP) net of all costs such as rebates, received by the provider, and discounts. NC Select Drugs administered in a Professional Outpatient setting shall be reimbursed directly to the provider.

Supplemental charges to cover the administration of the select drug shall be reimbursed based on the applicable fee schedule(s). NC Medicaid will not reimburse point of sale pharmacies, including Specialty Pharmacies directly for NC Select Drugs or their administration. The provider's designated representative responsible for billing shall attest the AAC reflects the actual costs incurred by the provider for the drug.

NC Select Drug reimbursement requires submission of an invoice showing the AAC of the drug. Drugs will be reimbursed at the lesser of AAC or the ASP. If the ASP is unavailable, reimbursement shall be AAC.

All drugs on the NC Select Drug List are carved out of 340B. Providers may not utilize 340B inventory for NC Medicaid members for those drugs listed on the NC Select Drug List.

All drugs included on the NC Select Drug List are subject to the special reimbursement methodology defined on these pages due to their cost.