

ROY COOPER • Governor KODY H. KINSLEY • Secretary JAY LUDLAM • Deputy Secretary, NC Medicaid

## SIGNATURE REQUEST MEMORANDUM

TO: Jay Ludlam

FROM: Ashley Blango, SPA Coordinator

**RE:** State Plan Amendment

Title XIX, Social Security Act Transmittal #2025-0004

#### Purpose

Attached for your review and signature is a Medicaid State Plan Amendment (**NC Select Drugs**) summarized below, and submitted on January 24, 2025, with a due date of January 31, 2025.

### Clearance

This amendment has been reviewed for both accuracy and completeness by:

Ashley Blango, Kathryn Horneffer, Lotta Crabtree, Adam Levinson, Melanie Bush

#### **Background and Summary of Request**

It is recommended that you sign this State Plan Amendment submission per Centers for Medicare and Medicaid Services (CMS) protocol as head of the Single State Agency administering the Medicaid program.

This SPA will establish 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.

The proposed effective date for the SPA is January 1, 2025.

Your approval of this State Plan Amendment is requested. If you have any questions or concerns, please contact me or Ashley Blango at 919-812-6145.

#### MEDICAL ASSISTANCE State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

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

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, <u>https://medicaid.ncdhhs.gov/nc-select-drug-list/download?attachment</u>, 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.

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, <u>https://medicaid.ncdhhs.gov/nc-select-drug-list/download?attachment</u>, 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.

TN No: <u>25-0004</u> Supersedes TN No: New **Approval Date:** 

Effective Date: 01/01/2025

## MEDICAL ASSISTANCE STATE: <u>NORTH CAROLINA</u> PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

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.

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, <u>https://medicaid.ncdhhs.gov/nc-select-drug-list/download?attachment</u>, 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.

Effective Date: 01/01/2025

#### State Plan under Title XIX of the Social Security Act Medical Assistance Program State: NORTH CAROLINA

#### PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

#### 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, <u>https://medicaid.ncdhhs.gov/nc-select-drug-list/download?attachment</u>, 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.

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

#### State: NORTH CAROLINA

Payments for Remedial Care and Services: Inpatient Hospital

#### 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, <u>https://medicaid.ncdhhs.gov/nc-select-drug-list/download?attachment</u>, 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.

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