



02/27/2025

Medication Restriction List

The following guidance describes rules for select drugs when coverage is restricted to a specific care setting.

Care Settings:

• Institutional Claims (IC):

Institutional claims (IC) are billed on an 837I/UB-04, must be eligible for a drug rebate*, and may be subject to specific drug restriction criteria**. Claims are paid per Diagnosis-Related Group (DRG) or Ratio Cost to Charge (RCC) methodology based on whether the drug was administered in the inpatient or outpatient care setting, respectively. The exceptions to this are as follows:

- Dialysis Institutional Claims: Please see Policy 1A-34 for specific guidance.
- NC Select Drug List***
- Professional Claims (PC):

Professional claims (PC) are billed on an 837P/CMS 1500, must be eligible for a drug rebate*, and are subject to the Physician Administered Drug Program Fee Schedule.

• Point of Sale Claims (POS):

Point of Sale claims (POS) are billed through the outpatient pharmacy at the time of dispensing, must be eligible for a drug rebate*, and are held to specific rules of drug restriction such as prior authorization, clinical criteria, and quantity limits. POS claims are paid per reimbursement logic defined in the State Plan Amendment. This care setting includes specialty pharmacies.

*Any exceptions allowed for rebate eligibility are described in clinical policy 1B and 9 and available under <u>Program Specific Clinical</u> <u>Coverage Policies</u>.

** See Policy <u>1S-13, Cell and Gene Therapies</u>.

***Please refer to the <u>NC Select Drug List</u> for a list of drugs that have additional requirements.

Drugs Restricted to POS:

- "Restricted" injectable products, which are administered by providers in the professional setting are covered ONLY on POS claims with prior authorization and/or clinical criteria being applied. These drugs are "restricted" to POS dispensing.
- For these restricted drugs, when billed in the Professional setting on a PC, the drug must be obtained from a POS pharmacy. The drug is paid as a POS claim. Only the administration fee is billable on the PC.
 - Drugs billed on ICs are not "restricted" to POS dispensing; however, an institution may choose to procure a drug from a POS pharmacy to be administered in the institutional setting. Prior authorization or clinical criteria will apply. Only the administration charge would be billed by IC.
 - Exception: Effective January 01, 2025, as outlined in the State Plan Amendment, if an institution procures a drug listed on the NC Select Drug List from a POS pharmacy, the institution must submit a medical claim directly to Medicaid for reimbursement of the drug's cost. The POS pharmacy is not permitted to submit the claim on behalf of the institution.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

| Drugs ONLY payable on Professional and Institutional claims | | | | | | |
|---|---|--|--|--|--|--|
| (NOT Payable on Point of Sale (POS) Claims) | | | | | | |
| Professional and Institutional Claims | Institutional Claims | | | | | |
| Adstiladrin [®] | Amtagvi[™] | | | | | |
| Crofab [®] | Policy 11A-17 - Car-T Cell Therapy applies | | | | | |
| • Spinraza [®] | for the following: | | | | | |
| • Spravato [®] | ○ Abecma [®] | | | | | |
| | Breyanzi[®] | | | | | |
| Please see the <u>PADP Catalog</u> for a full list of | Carvykti[®] | | | | | |
| covered drugs for professional claims. | ○ Kymriah [®] | | | | | |
| | ○ Tecartus [®] | | | | | |
| | ○ Yescarta [®] | | | | | |
| | Policy <u>1S-13</u>, Cell and Gene Therapies | | | | | |
| | Casgevy[™] | | | | | |
| | o Kebildi™ | | | | | |
| | ○ Lenmeldy[™] | | | | | |
| | Lyfgenia[™] | | | | | |
| | ○ Luxturna [®] | | | | | |
| | Hemgenix[®] | | | | | |
| | ○ Elevidys [®] | | | | | |
| | o Roctavian[™] | | | | | |
| | ○ Skysona [®] | | | | | |
| | Zolgensma[®] | | | | | |
| | Zynteglo[®] | | | | | |
| | Imlygic[®] | | | | | |
| | Lantidra [™] | | | | | |
| | Omisirge [®] | | | | | |
| | Provenge [®] | | | | | |
| | Rethymic [®] is covered per <u>Policy 11B-9</u> <u>Thymus Tissue Implantation</u> Tecelra [®] | | | | | |
| | | | | | | |
| | | | | | | |
| | • Zulresso [®] | | | | | |

| Drugs Payable on POS and Institutional Claims (NOT Payable on Professional Claims) | | | | |
|---|---|---|--|--|
| No PA/CC required Intentionally left | Drug-Specific PA Form Adbry® | Standard PA Form | PA with Special Circumstances Ocrevus [®] – uses | |
| blank. | Adory^a Aduhelm[®] Amondys 45[®] Cinryze[®] Dupixent[®] Exondys 51[®] Fasenra[®] Haegarda[®] Kevzara[®] Orladeyo[®] Nucala[®] Takhzyro[®] Tezspire[®] Viltepso[®] Vyepti[®] Vyondys 53[®] Xolair[®] | Intentionally left blank. | standard PA form – try 2 preferred agents. However, IF diagnosis is Primary Progressive MS, may write PPMS on form and bypass trial of 2 preferred agents. <u>Synagis</u> [®] – Inpatient coverage paid per DRG (no PA required) Outpatient coverage paid by POS billing only (PA required) | |

| Date | Section Revised | Change |
|-------------------|--|---|
| February 2025 v1 | "Drugs ONLY Payable on Professional and Institutional Claims" Table | Added the following to "institutional claims": Kebildi™. Removed Beqvez. Moved Lenmeldy™ under policy 1S-13, Cell and Gene Therapy. |
| November 2024 v3 | Care Settings and Drugs Restricted to POS. | Updated to align to Policy and State Plan Amendment changes which will be effective 01/01/2025. |
| November 2024 v2 | "Drugs ONLY Payable on Professional and Institutional Claims" Table | Added the following to "Institutional Claims": Becvez, Casgevy, Elevidys, Imlygic, Lenmeldy, Lyfgenia, Omisirge, Provenge, Tecelra, Amtagvi, and Zolgensma. Removed Luxturna from "Professional and Institutional Claims"; added Luxturna to "Institutional Claims". Updated formatting and grammatical error(s). |
| November 2024 v1 | "Drugs Payable on POS and Institutional Claims" Table | Moved or added the following to "Drug-Specific PA Form": Adbry, Cinryze, Haegarda, Orladeyo, Takhzyro, and Tezpire. Removed Elevidys, Lyfgenia. Casgevy, and Zolgensma from the table. Updated the "No PA/CC required" and "Standard PA Form" section. Updated formatting. |
| September 2024 v1 | Added "Medication Restriction List Implementation/Revision Information" Table. | Table promulgated. |
| March 2024 v1.1 | "Drugs ONLY Payable on Professional and Institutional Claims" Table | Removed Vyjuvek from "Professional and Institutional Claims." |
| March 2024 v1 | "Drugs ONLY Payable on Professional and Institutional Claims" Table | Added the following under "Professional and Institutional Claims: Vyjuvek, Adstiladrin. Added the following under "Institutional Claims": Lantidra, Roctavian, Hemgenix. |

Medication Restriction List Implementation/Revision Information:

| March 2024 v1 | "Druge Deveble on DOC and | Added the following to "Standard |
|----------------|--------------------------------|-----------------------------------|
| March 2024 v1 | "Drugs Payable on POS and | Added the following to "Standard |
| | Institutional Claims" Table | PA Form": Elevidys, Lyfgenia, |
| | | Casgevy. |
| March 2024 v1 | Added version nomenclature | Designated as Version 1. |
| September 2023 | "Drugs ONLY Payable on | Added the following drugs to |
| | Professional and Institutional | Institutional Claims only: |
| | Claims" Table | Rethymic, Zynteglo, Skysona. |
| September 2023 | All sections | Updated format, definitions, and |
| | | added tables. |
| September 2022 | Separated "Professional and | Added Tecartus to "IC claims" |
| | Institutional Claims" and | only. |
| | "Institutional Claims Only" | |
| | Section. | |
| September 2022 | Point-of-Sale Section | Updated formatting. |
| September 2022 | All sections | Updated formatting and title |
| | | names for clarity. |
| March 2022 | All sections | Initial promulgation of document. |