

Kyxata™ (carboplatin) (Intravenous)

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Last Review Date: 10/02/2025

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Dates Reviewed: 10/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180-days).
- Renewal: Prior authorization validity may be renewed every 6 months (180-days) thereafter, unless otherwise specified.
 - Ovarian Cancer initial therapy: Prior authorization validity may NOT be renewed.

II. Dosing Limits

A. Max Units (per dose and over time) [HCPCS Unit]:

- 900 mg every 4 weeks (28-days)

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Carboplatin is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>; **AND**

Ovarian Cancer † ^{1,2}

- Used as initial therapy for advanced disease in combination with cyclophosphamide; **OR**
- Used as subsequent therapy for recurrent platinum-sensitive advanced disease as a single agent

Kyxata is a solution in a multi-dose vial formulation of carboplatin approved via 505(b)(2) NDA referencing Paraplatin. This product is nearly identical to the listed product, Paraplatin. No new clinical or nonclinical data were provided with this submission, as no studies were conducted for this 505(b)(2) application.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,4-8}

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, severe myelosuppression (leukopenia, neutropenia, and thrombocytopenia), severe nausea/vomiting, severe peripheral neuropathy, etc.

V. Dosage/Administration ¹

| Indication | Dose |
|----------------|---|
| Ovarian Cancer | <p><u>Initial therapy</u></p> <p>Administer 300 mg/m² -OR- AUC of 4 mg/mL·min to 6 mg/mL·min* intravenously in combination with cyclophosphamide 600 mg/m² intravenously on Day 1 every 4 weeks for each cycle. Administer up to six cycles or until disease progression or unacceptable toxicity occurs.</p> <p><u>Subsequent therapy</u></p> <p>Administer 360 mg/m² -OR- AUC of 4 mg/mL·min to 6 mg/mL·min* intravenously on Day 1 every 4 weeks for each cycle until disease progression or unacceptable toxicity occurs.</p> <p>* Carboplatin Dose (mg) = Target Area Under the Curve (AUC) (mg/mL/min) x (GFR + 25). Glomerular filtration rate (GFR) is commonly calculated as estimated creatinine clearance (CLcr) using the Cockcroft-Gault formula. For older adults, calculate the dose based on AUC to reduce risk of severe adverse reactions.</p> |

VI. Billing Code/Availability Information

HCPCS Code(s)

- J9999 – Not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals

NDC(s)

- Kyxata 20 mg/2 mL solution in a multiple-dose vial: 83831-0140-xx
- Kyxata 80 mg/8 mL solution in a multiple-dose vial: 83831-0141-xx
- Kyxata 500 mg/50 mL solution in a multiple-dose vial: 83831-0142-xx

VII. References

1. Kyxata [package insert]. Parsippany, NJ; Avyxa Pharma, LLC.; August 2025. Accessed August 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for carboplatin. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor | Conclusion |
|----------------------------|-----------------------|
| Indication | Yes: Consider for PA |
| Safety and efficacy | Yes: Consider for PA |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|---|
| C48.1 | Malignant neoplasm of specified parts of peritoneum |
| C48.2 | Malignant neoplasm of peritoneum, unspecified |
| C48.8 | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.3 | Malignant neoplasm of parametrium |
| C56.9 | Malignant neoplasm of unspecified ovary |
| C57.00 | Malignant neoplasm of unspecified fallopian tube |
| C57.01 | Malignant neoplasm of right fallopian tube |
| C57.02 | Malignant neoplasm of left fallopian tube |
| C57.10 | Malignant neoplasm of unspecified broad ligament |
| C57.11 | Malignant neoplasm of right broad ligament |
| C57.12 | Malignant neoplasm of left broad ligament |
| C57.20 | Malignant neoplasm of unspecified round ligament |
| C57.21 | Malignant neoplasm of right round ligament |
| C57.22 | Malignant neoplasm of left round ligament |
| C57.3 | Malignant neoplasm of parametrium |
| C57.4 | Malignant neoplasm of uterine adnexa, unspecified |

| ICD-10 | ICD-10 Description |
|--------|--|
| C57.7 | Malignant neoplasm of other specified female genital organs |
| C57.8 | Malignant neoplasm of overlapping sites of female genital organs |
| C57.9 | Malignant neoplasm of female genital organ, unspecified |
| Z85.43 | Personal history of malignant neoplasm of ovary |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |