

Kyxata™ (carboplatin) (Intravenous)

Document Number: IC-0809

Last Review Date: 10/02/2025

Date of Origin: 10/02/2025

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

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

- 900 billable units 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><i>* 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 (CL_{cr}) using the Cockcroft-Gault formula. For older adults, calculate the dose based on AUC to reduce risk of severe adverse reactions.</i></p>

VI. Billing Code/Availability Information

HCPCS Code(s)

- C9308 – Injection, carboplatin (avyxa), 1 mg; 1 billable unit = 1 mg (*Effective 01/01/2026*)
- J9999 – Not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals (*Discontinue use on 01/01/2026*)

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 National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2025.

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

ICD-10	ICD-10 Description
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
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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