

BILLING AND CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.

Please see Important Safety Information on pages 3 and 13-14 and full Prescribing Information for KYXATA™ including BOXED WARNINGS.



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The contents herein provide general coverage, coding, and payment information about KYXATA™. The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA™ does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNINGS

INDICATIONS

Initial Treatment of Advanced Ovarian Carcinoma

KYXATA™, as part of a combination regimen, is indicated for the initial treatment of adults with advanced ovarian carcinoma.

Recurrent Advanced Ovarian Carcinoma

KYXATA is indicated for treatment of adults with ovarian carcinoma recurrent after prior chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS

- Serious and life-threatening hypersensitivity reactions, including anaphylaxis, can occur with KYXATA within minutes of administration during any cycle.
- Immediately withhold KYXATA for severe hypersensitivity reactions and administer appropriate treatment for management of the hypersensitivity reaction.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity, including anaphylaxis, can occur in patients treated with KYXATA. Hypersensitivity reactions occurred in 2% of patients treated with carboplatin and included rash, urticaria, erythema, pruritus, bronchospasm, and hypotension. These adverse reactions may occur within minutes of administration and during any cycle. There is an increased risk of allergic reactions, including anaphylaxis, in patients previously exposed to platinum-based therapy or after 6 cycles of carboplatin.

Monitor patients receiving KYXATA for hypersensitivity reactions. Ensure supportive equipment and medications are available to treat severe hypersensitivity reactions. Severe hypersensitivity reactions may require immediate discontinuation of KYXATA.

Myelosuppression

Myelosuppression (leukopenia, neutropenia, and thrombocytopenia) is dose-dependent, may be severe, and can cause fatal infections or hemorrhage in patients treated with KYXATA.

Grade 3-4 neutropenia occurred in 16% of the patients treated with carboplatin as a single agent. Grade 3-4 thrombocytopenia occurred in 25% of patients with ovarian cancer. Febrile neutropenia may occur. Blood product transfusions were required in 26% (44% of pretreated) of patients with ovarian cancer treated with carboplatin as a single agent. Infectious and hemorrhagic complications each occurred in 5% of the patients treated with carboplatin as a single agent. Fatal adverse reactions occurred in less than 1% of patients treated with carboplatin as a single agent.

Patients with impaired kidney function are at increased risk of severe myelosuppression and may require dosage modifications.

Monitor complete blood counts prior to each cycle and as clinically indicated. If myelosuppression occurs, modify KYXATA dosage when required.

KYXATA™ (carboplatin) Injection

Ordering Information

To order KYXATA™ (carboplatin) Injection, please contact one of these authorized specialty distributors and use the appropriate order number:





80 mg/8 mL NDC: 83831-0141-08 500 mg/50 mL NDC: 83831-0142-50

Institutions/Hospitals	80 mg/8 mL	500 mg/50 mL
Cardinal Health Specialty	6051080	6051098
CENCORA - ASD Healthcare	10302720	10302740
McKesson Plasma & Biologics	Not Available	3057718
Physician Offices	80 mg/8 mL	500 mg/50 mL
Cardinal Health Specialty	6051080	6051098
Oncology Supply	10302702	10302730
McKesson Specialty Health	Not Available	5021021

Highlights¹

- · Supplied in multi-dose vials
- · No reconstitution required and ready to dilute solution
- Ready to add to intravenous infusion solution with different options:
 - 5% Dextrose Injection, USP
 - · 0.9% Sodium Chloride Injection, USP
- · Diluted infusion solution is stable for a maximum of 8 hours
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)
- Not made with natural rubber



Unique J-Code Coming January 1, 2026

XVYXASSIST™

Simplifying Patient Access, Providing Comprehensive Support.

AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services*

- **Senefit verification**
- **Y** Prior authorization requirements
- Appeals process information
- **∀** Referrals to 501(c)(3) foundations when applicable
- Free product assistance (uninsured or underinsured), bridge supply (coverage delays)
- Product replacement
- **Copay assistance**

COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as

\$0

OR

per dose*

TO ENROLL, PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS



Phone

866-939-8927 Monday through Friday 8 AM to 8 PM ET

CALL NOW



Online

Click on the link below to begin your online enrollment

ENROLL NOW



Fax

Download, print and fax the completed enrollment form to 833-852-3420

DOWNLOAD NOW

OR

^{*}For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

KYXATA™ Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA does not recommend using any particular diagnosis code in billing situations for KYXATATM (carboplatin) Injection. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs

National Drug Codes (NDC) are unique product identifiers used for drugs and biologicals. The Centers for Medicare & Medicaid Services (CMS) and private payors often require an NDC as part of the billing claim form. If the NDC Package code is less than 11 digits, the code must be padded with leading zeros, as shown below.²

KYXATA™ NDC¹	Strength	Package
83831-0141-08	80 mg/8 mL (10 mg/mL)	1 multiple-dose vial in 1 carton
83831-0142-50	500 mg/50 mL (10 mg/mL)	1 multiple-dose vial in 1 carton

HCPCS Code³

HCPCS Level II codes are used to identify most drugs and biologics administered in the office. Correct coding requires reporting the most specific code to describe the service accurately. Not otherwise classified (NOC) codes are used only when a more specific HCPCS code is not available or assigned.

KYXATA™ J-Code	Description
J9999	Not otherwise classified, antineoplastic drugs

To correctly process a claim using a NOC code, you may need to include invoice and clinical notes.4

J-Code Billing Unit Conversion³⁻⁶

Not Otherwise Classified (NOC) codes, such as J9999, are priced manually. When billing unlisted codes, the unit of service equals one (1), and the following details must be entered into Item 19 of the CMS-1500 or electronic claim equivalent.

- · Name of the drug
- · Dose administered (mg, cc, etc.) and strength of dosage, if appropriate
- Route of administration (IV, IM, SC, PO, etc.)
- National Drug Code (NDC)

Some payers may require the NDC to be entered in Item 19 on the CMS 1500 form. Medicare determines the proper payment of NOC drugs and biologicals based on narrative information listed above, rather than the number of units billed.^{5,6}

Until a permanent J-Code is assigned, KYXATA™ is billed using one (1) unit of service.5

Important: List one unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Claims for NOC drugs and biologicals may be rejected if any of the information listed above is missing or if the NOC code is billed with more than one unit of service.⁵

KYXATA™ is a platinum-based drug indicated in adults:

- · As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma.
- · As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy.1

Example:

The recommended dosage of KYXATA[™] for <u>recurrent</u> advanced ovarian carcinoma as a single agent is KYXATA[™] 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.¹

An adult female patient with a BSA of 1.73 m² received 623 mg of KYXATA™ administered intravenously as a single agent for the treatment of recurrent advanced ovarian cancer.

The J-Code billing unit is one (1), and an example of information to include in Item 19 is:⁵ **KYXATA 623mg IV 83831014250**

CPT Drug Administration Codes

CPT codes are used to bill drug administration services in the physician's office and other outpatient settings.⁷ The recommended dosage of KYXATA™ depends on body surface area and whether it is used alone or as a part of a combination regimen. Please code based on the start and stop times listed in the patient's medical chart.¹

KYXATA™ is supplied as a multiple-dose vial.¹ Medicare will not pay for drug waste on multiple-dose vials, so the JW and JZ modifiers are not applicable in the billing of KYXATA™.8

CPT Code	Description ⁹	Place of Service (POS) ¹⁰
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug	Physician Office (11) Off Correct Outpetient Hearital (10)
96417	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug), up to 1 hour	Off-Campus Outpatient Hospital (19) On-Campus Outpatient Hospital (22)

CPT codes, descriptions, and other data are copyright 2025 American Medical Association. All Rights Reserved. Applicable FARS/ HHSARS apply. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Revenue Codes

Claim Item	Revenue Code ¹¹	Description	Place of Service (POS) ¹⁰
KYXATA TM	0636	Drugs Requiring Detailed Coding	Off-Campus Outpatient Hospital (19)
Drug Administration	0335	Chemotherapy Administration – IV	On-Campus Outpatient Hospital (22)

ICD Diagnosis Codes

KYXATA™ is a platinum-based drug indicated in adults:

- As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma.
- As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy¹

It is best practice to code the most specific ICD-10-CM Code within the indication to justify medical

International Classification of Disease, 10th Edition, Clinical Modification Codes for KYXATA™ Injection					
Indication ICD-10-CM Codes					
Ovarian Cancer ¹² C56.1, C56.2, C56.3, C56.9					

ICD Diagnosis Codes by Indication

ICD-10-CM coding for KYXATA™ Injection varies greatly by payer. Please check with each payer to ascertain the best coding for the KYXATA™ Injection according to their policy.

Ovarian Cancer: ICD-10-CM Diagnosis Coding ¹²	
ICD-10 Code	Descriptor
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary

Sample UB-04 / CMS 1450 Claim Form^{3,9,11-13}

Form Locator (FL) 42

(Electronic Claim Form = Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for KYXATA™ Injection to your revenue code, 0636.

Additionally, enter an appropriate revenue code for the administration service, such as 0335 for chemotherapy administration-IV or others based on the cost center where the service was performed.

FL 43

(NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed.

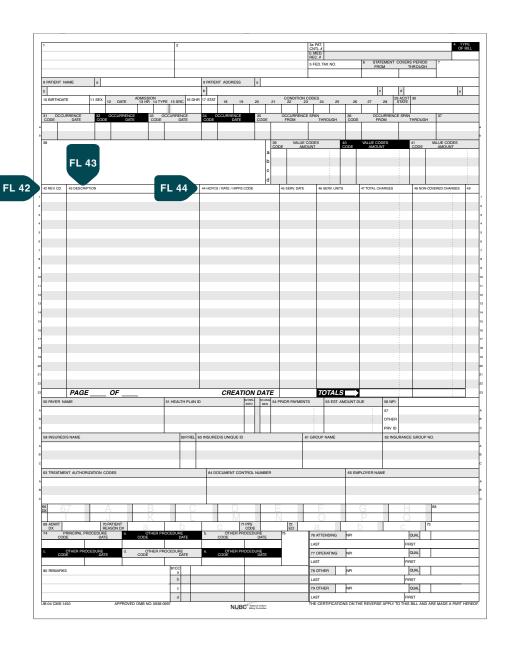
If required, list the N4 indicator first, then the 11-digit NDC code. In the third place, list the NDC unit measurement code and, last, the quantity.

FL 44

(Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP)

Enter the appropriate HCPCS code: J9999, Not otherwise classified, antineoplastic drugs.

For administration, enter the appropriate code or codes for intravenous administration. As an example, chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug requires CPT code 96413.*



*CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

FL 45

(Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46

(Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed. Enter the number of service units for each item.

FL 63

(Electronic Claim Form = Loop 2300, REF/G1/02):

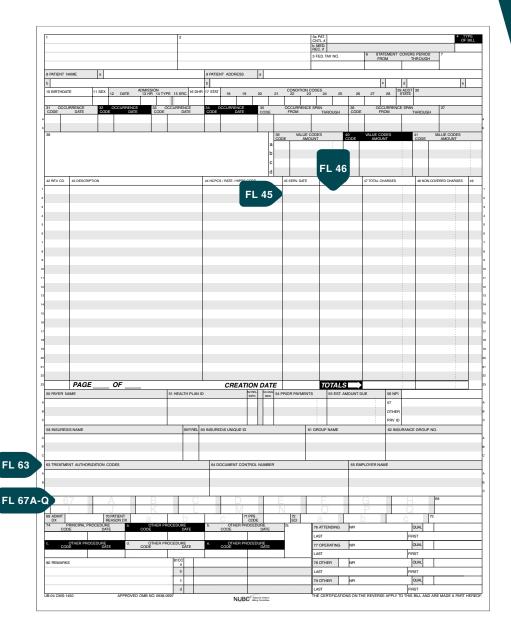
Enter treatment authorization code.

FL 67A-Q

(Electronic Claim Form Loop 2300, H101-2 (H101-1=BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible.

The code listed here is an example: C56.1 Malignant neoplasm of right ovary.



Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 16, 2025. https://www.palmettogba.com/pal-%20metto/ providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf

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THIS INFORMATION IS PROVIDED FOR EDUCATIONAL PURPOSES ONLY AND IS NOT A GUARANTEE OF COVERAGE. IT IS THE SOLE RESPONSIBILITY OF THE HEALTH CARE PROVIDER TO SELECT THE PROPER CODES AND ENSURE THE ACCURACY OF ALL STATEMENTS USED IN SEEKING COVERAGE AND REIMBURSEMENT FOR AN INDIVIDUAL PATIENT.

Sample CMS 1500 Claim Form^{3,5,6,9,12}

Item 19

(Electronic Claim Form = Loop 2400, Segment SV101-2) Additional claim information

When billing a Not Otherwise Classified code, providers must indicate the following: The name of the drug, total dosage (plus strength of dosage, if appropriate), and method of administration. Some payers may require NDC number.

Item 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record.

An example code for this drug is C56.1 Malignant neoplasm of right ovary.

Use Item 21 B-L fields for secondary diagnoses.

Item 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists

Item 24A-B

(Electronic Claim Form: Item 24A (Electronic Claims = Loop 2400, DTP02; Item 24 B (Loop 2300/2400, Segment CLM05-1/SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Physician Office = 11.

If required, in the shaded area, enter the N4 indicator first, then the 11-digit NDC code.

In the third space, list the unit measurement code, and last, the quantity.

	HEALTH INSURANCE CLAIM FORM		
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		M F	
	5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED 7. II Self Spouse Child Other	INSURED'S ADDRESS (No., Street)
	CITY STATE	8. RESERVED FOR NUCC USE CIT	TY STATE
	ZIP CODE TELEPHONE (Include Area Code)	ZIP	CODE TELEPHONE (Include Area Code)
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	c. RESERVED FOR NUCCUSE	C. OTHER ACCIDENT?	INSURANCE PLAN NAME OR PROGRAM NAME
		YES NO	
	d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC) d. II	IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO #yes, complete items 9, 9a, and 9d.
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	to process this claim. I also request payment of government benefits eithe below.	to myself or to the party who accepts assignment	services described below.
	SIGNED	DATE	SIGNED
	14. DATE OF CURRENT ILLNESS, INJURY, OF PREGNANCY (LMP) 15	OTHER DATE MM DD YY 16.	DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY
	17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17	. 18.	HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM DD YY TO MM DD YY
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Item 24D

(Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code: J9999, Not otherwise classified, antineoplastic drugs.

For administration, enter the appropriate code or codes for intravenous administration. As an example, chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug requires CPT code 96413.*

Item 24E

(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Item 21.

Item 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of J-Code service units for each item.

- n											
EALTH INSURANC											
PROVED BY NATIONAL UNIFORM	CLAIM COMMITTEE (NUC	XC) U2/12									PICA T
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*CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 16, 2025. https://www.palmettogba.com/pal-%20metto/ providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/\$FILE/EDI_837I_v5010A2_crosswalk.pdf

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IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Nausea and Vomiting

KYXATA can induce emesis, which can be more severe in patients previously receiving emetogenic therapy, and is dose-dependent. Administer pre-treatment and post-treatment antiemetics as clinically indicated.

Monitor and manage patients with antiemetics, or fluid replacement, as clinically indicated. Consider withholding or delaying KYXATA if nausea or vomiting is severe or intolerable and is not responsive to antiemetics.

Peripheral Neuropathy

Peripheral neuropathy, including paresthesia, can occur in patients treated with KYXATA.

Peripheral neuropathy occurred in 4% of patients receiving carboplatin as a single agent (6% of pretreated patients with ovarian cancer). Peripheral neuropathy occurred in 10% of patients older than 65 who were previously treated with carboplatin.

Prolonged treatment, treatment with other platinum-containing therapies, or use in combination with other drugs that cause peripheral neuropathy may increase the incidence or severity of peripheral neuropathy.

Monitor for signs and symptoms of peripheral neuropathy. Withhold, reduce, or discontinue KYXATA depending on the severity and persistence of peripheral neuropathy as clinically indicated.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, KYXATA can cause fetal harm when administered to a pregnant woman. Administration of carboplatin to pregnant rats caused adverse developmental outcomes, including embryo-fetal lethality and structural abnormalities.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with KYXATA and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with KYXATA and for 3 months after the last dose.

ADVERSE REACTIONS

Most common adverse reactions, including laboratory abnormalities, in patients with advanced ovarian cancer who received KYXATA in combination with cyclophosphamide (≥30%) are leukopenia, neutropenia, nausea and vomiting, anemia, thrombocytopenia, hypomagnesemia, other gastrointestinal adverse reactions, alopecia, asthenia, and pain.

Most common adverse reactions, including laboratory abnormalities, in patients with recurrent ovarian cancer who received KYXATA as a single agent (≥30%) are nausea and vomiting, anemia, neutropenia, thrombocytopenia, hyponatremia, hypomagnesemia, hyperphosphatasemia, and hypocalcemia.

DRUG INTERACTIONS

Use with Aminoglycosides: Avoid concomitant use of aminoglycosides with KYXATA. Concomitant use of KYXATA with aminoglycosides increased renal toxicity and ototoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy: Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation: Advise women not to breastfeed during treatment with KYXATA and for 1 week after the last dose.

Females and Males of Reproductive Potential: Advise females of reproductive potential to use effective contraception during treatment with KYXATA and for 6 months after the last dose; and advise male patients with female partners of reproductive potential to use effective contraception during treatment with KYXATA and for 3 months after the last dose.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Geriatric Use: Elderly patients treated with carboplatin were more likely to develop severe thrombocytopenia or peripheral neuropathy than younger patients. Consider renal function when selecting the KYXATA dose for older adults since they often have decreased renal function. To minimize the risk of toxicity in older adults, calculate the dose based on AUC.

Renal Impairment: Reduce the dose for patients with creatinine clearance (CL_{cr}) of 16 to 59 mL/min who will be administered a dose based on body surface area. A recommended dose of KYXATA has not been established for patients with a CL_{cr} <16 mL/min.

DOSAGE AND ADMINISTRATION GUIDELINES

It is very important that the dosage, preparation and administration instructions provided in the full prescribing information are strictly followed to reduce the risk of severe adverse reactions.

Administer KYXATA in a setting where cardiopulmonary resuscitation medication and equipment are available.

Premedicate patients with antiemetics prior to each infusion of KYXATA for the prevention of nausea and vomiting. Continue antiemetics following infusion as needed.

Do not use needles or intravenous infusion sets containing aluminum; aluminum reacts with carboplatin causing precipitate formation and a loss of potency.

OVERDOSAGE

There is no known antidote for KYXATA overdosage. The anticipated complications of overdosage would be secondary to bone marrow suppression and/or hepatic toxicity. Patients receiving overdosages of carboplatin experienced severe liver function test abnormalities. Loss of vision, which can be complete for light and colors, has been reported after the use of carboplatin at doses higher than the recommended approved dosage for KYXATA. Vision recovers totally or to a significant extent after discontinuation of carboplatin. Clinically significant hearing loss has been reported to occur in pediatric patients when carboplatin was administered at higher than approved recommended doses for KYXATA and in combination with other ototoxic agents. KYXATA is removed by dialysis.

Closely monitor patients suspected of receiving an overdose, including for the adverse reactions described above, and administer appropriate supportive treatment.

Please see KYXATA full Prescribing Information, including BOXED WARNINGS.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Notes	

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