OXDERYS™
(doxorubicin hydrochloride injection)

BILLING & CODING GUIDE

AVYXA

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The contents herein provide general coverage, coding, and payment information about OXDERYS. 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), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA Pharma, LLC 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

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

Adjuvant Breast Cancer

OXDERYS™ is indicated as a component of multi-agent adjuvant chemotherapy for treatment of adults with axillary lymph node involvement following resection of primary breast cancer.

Other Cancers

OXDERYS is indicated for the treatment of

- acute lymphoblastic leukemia
- acute myeloblastic leukemia
- Hodgkin lymphoma
- non-Hodgkin lymphoma (NHL)
- metastatic breast cancer
- metastatic Wilms' tumor
- metastatic neuroblastoma
- metastatic soft tissue sarcoma
- metastatic bone sarcoma
- metastatic ovarian carcinoma
- metastatic transitional cell bladder carcinoma
- metastatic thyroid carcinoma
- metastatic gastric carcinoma
- metastatic bronchogenic carcinoma

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOMYOPATHY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION

- **Cardiomyopathy: Myocardial damage, including acute left ventricular failure, can occur with OXDERYS. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 1% to 20% for cumulative doses ranging from 300 mg/m^2 to 500 mg/m^2 when OXDERYS is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with OXDERYS.**
- **Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including OXDERYS.**
- **Extravasation and Tissue Necrosis: Extravasation of OXDERYS can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area.**
- **Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur.**

CONTRAINDICATIONS

OXDERYS is contraindicated in patients with:

- Severe myocardial insufficiency
- Recent (occurring within the past 4-6 weeks) myocardial infarction
- Severe persistent drug-induced myelosuppression
- Severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin level greater than 5 mg/dL)
- Severe hypersensitivity reaction to doxorubicin hydrochloride, including anaphylaxis

WARNINGS AND PRECAUTIONS

Cardiomyopathy and Arrhythmias

Cardiomyopathy

OXDERYS can result in myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy is generally proportional to the cumulative exposure. Include prior doses of other anthracyclines or anthracenediones in calculations of total cumulative dosage for OXDERYS. Cardiomyopathy may develop during treatment or up to several years after completion of treatment and can include decrease in LVEF and signs and symptoms of congestive heart failure (CHF). The probability of developing cardiomyopathy is estimated to be 1 to 2% at a total cumulative dose of 300 mg/m^2 of doxorubicin hydrochloride, 3 to 5% at a dose of 400 mg/m^2, 5 to 8% at a dose of 450 mg/m^2, and 6 to 20% at a dose of 500 mg/m^2, when doxorubicin hydrochloride is administered every 3 weeks. There is an additive or potentially synergistic increase in the risk of cardiomyopathy in patients who have received radiotherapy to the mediastinum or concomitant therapy with other known cardiotoxic agents, such as cyclophosphamide and trastuzumab.

Pericarditis and myocarditis have also been reported during or following doxorubicin hydrochloride treatment.

Assess left ventricular cardiac function (e.g., MUGA or echocardiogram) prior to initiation of OXDERYS, during treatment to detect acute changes, and after treatment to detect delayed cardiotoxicity. Increase the frequency of assessments as the cumulative dose exceeds 300 mg/m^2. Use the same method of assessment of LVEF at all time points. Discontinue OXDERYS in patients who develop signs or symptoms of cardiomyopathy.

Consider the use of dexrazoxane to reduce the incidence and severity of cardiomyopathy due to OXDERYS administration in patients who have received a cumulative OXDERYS dose of 300 mg/m^2 and who will continue to receive OXDERYS.

Arrhythmias

OXDERYS can result in arrhythmias, including life-threatening arrhythmias, during or within a few hours after OXDERYS administration and at any time point during treatment. Tachyarrhythmias, including sinus tachycardia, premature ventricular contractions, and ventricular tachycardia, as well as bradycardia, can occur. Electrocardiographic changes, including non-specific ST-T wave changes, atrioventricular and bundle-branch block can also occur. These electrocardiographic changes may be transient and self-limited and may not require a dosage modification of OXDERYS.

OXDERYS™
(doxorubicin hydrochloride injection)

Ordering Information

To order OXDERYS™ (doxorubicin hydrochloride injection), please contact one of the authorized specialty distributors below:



40 mg/20 mL (2 mg/mL)
NDC: 83831-0161-20



160 mg/80 mL (2 mg/mL)
NDC: 83831-0162-80

CardinalHealth cencora McKESSON BioCare People who care.

Highlights[1]

- Supplied in 40 mg/20 mL and 160 mg/80 mL multi-dose vials
- No reconstitution required and ready-to-dilute solution
- Ready to add to intravenous infusion solution with different options:
  - 0.9% Sodium Chloride Injection, USP
  - 5% Dextrose Injection, USP
- Diluted infusion solution is stable for 24 hours at room temperature up to 25°C (77°F) or refrigerated at 2°C to 8°C (36°F to 46°F)
- Partially used vials are stable for up to 28 days when stored in the original carton refrigerated at 2°C to 8°C (36°F to 46°F)

J-CODE

J9999

Unique J-Code Expected July 2027

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

AVYXASSIST®

Simplifying patient access, providing comprehensive support

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

- **Benefit verification**
- **Prior authorization requirements**
- **Appeals support**
- **Claims support**
- **Referrals to 501(c)(3) foundations**
- **Free product assistance**
- **Bridge supply**
- **Product replacement**
- **Copay assistance**

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

To enroll, please choose one of the following options.

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

CALL NOW

Click on the link below to begin online enrollment

ENROLL NOW

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

DOWNLOAD NOW

Commercially eligible patients prescribed **an AVYXA Pharma, LLC product** may pay as little as

$0 per dose*



Our dedicated AVYXASSIST Patient Access Specialists work collaboratively with you to explore tailored affordability solutions. AVYXA Pharma, LLC aims to facilitate financial accessibility for eligible patients in need.

ENROLL NOW

Copay Program Details for Eligible Patients

In some cases, the patient out-of-pocket cost for their AVYXA Pharma, LLC product could be as low as $0.*

- Up to $25,000 per patient, per drug.

*Please visit **avyxassist.com/copay-assistance-program** to see full Terms and Conditions.

Additional Assistance

Patients without insurance or who do not qualify for copay assistance through AVYXASSIST may qualify for free product assistance. Call an AVYXASSIST Patient Access Specialist to learn more.

Call 866-939-8927 or Fax 833-852-3420 | Monday through Friday, 8:00 AM to 8:00 PM ET

Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA Pharma, LLC 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 Pharma, LLC does not recommend using any particular diagnosis code in billing situations for OXDERYS™ (doxorubicin hydrochloride injection). The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs for OXDERYS Injection

National Drug Codes (NDC) are unique product identifiers used for drugs and biologicals. The Centers for Medicare & Medicaid Services (CMS) and private payers often require an NDC on 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] Be sure to include the NDC qualifier, NDC unit of measure and number of NDC units when submitting claims. The NDC Unit of Measure for this product is ML (liquid or solution).

NDC[1]	Strength	Vial Size
83831-0161-20	40 mg/20 mL (2 mg/mL)	Multiple-dose vial in 1 carton
83831-0162-80	160 mg/80 mL (2 mg/mL)	Multiple-dose vial in 1 carton

HCPCS Codes

HCPCS Level II codes are used to identify most drugs and biologics administered in an office setting. Correct coding requires reporting the most specific code to describe the service accurately.[3] Not otherwise classified (NOC) and unclassified codes are used only when a more specific HCPCS code is not available or assigned.[4]

OXDERYS Injection J-Code[4]

J-Code	Description
J9999	Not otherwise classified, antineoplastic drugs

For Medicare to properly reimburse unclassified or NOC drugs, providers must include the following supplemental information in the 2400/SV101-7 data element or Item 19 of the CMS-1500 form:

- The name of the drug,
- The total dosage (plus the strength of the dosage, if appropriate), and
- The method of administration.

Some payers may require entering the NDC in Item 19 of the CMS-1500 form. Medicare determines the proper payment for unclassified drugs and biologicals based on the narrative information listed above, not the number of units billed.[5]

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

Service Units

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

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

This billing is used in traditional Medicare billing. If you are unsure, check with your payers about their unit requirements.

Modifiers

A medical coding modifier is two characters (letters or numbers) appended to a CPT or HCPCS Level II code. Modifiers provide additional information about the medical procedure or service without changing the definition of the code. Using modifiers allows healthcare providers to specify specific circumstances, such as the route of administration, wasted product, and other relevant details.[6]

OXDERYS is supplied as a multi-dose vial, so no drug waste modifiers - JW, JZ - are required.[7]

340B Drug Pricing Modifier[8]

Modifier	Description
TB	Drug or biological acquired with 340b drug pricing program discount, reported for informational purpose

The "TB" modifier is used for informational purposes to identify drugs purchased through the 340B program. This enables CMS to accurately implement the Part B inflation rebate program established by the Inflation Reduction Act of 2022, as 340B drugs are excluded from the inflation rebate calculation. The "TB" modifier is proposed to change in 2027, please verify CMS guidelines prior to billing.[9]

CPT Drug Administration Codes

CPT codes bill for drug administration services in the physician's office and other outpatient settings. Administration of OXDERYS varies by indication and usage. Please code based on the start and stop times listed in the patient's medical chart.[10]

OXDERYS administration dosage, frequency, and cycle vary. See package insert.[1]

CPT Code[11]	Description
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

CPT codes, descriptions, and other data are copyright 2026 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[12]

Claim Item	Revenue Code	Description
OXDERYS™ Infusion	0636	Drugs requiring detailed coding
Drug Administration	0335	Chemotherapy administration - IV
	0331	Chemotherapy administration - injection

Place of Service (POS) Codes[13]

Place of service (POS) codes are used on professional claims to specify the entity where service(s) are rendered.

Place of Service	Code	Description
Physician Office	11	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
Off-Campus Outpatient Hospital	19	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
On-Campus Outpatient Hospital	22	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

ICD-10-CM Diagnosis Coding

OXDERYS is an anthracycline topoisomerase inhibitor indicated:[1]

- as a component of multi-agent adjuvant chemotherapy for treatment of adults with axillary lymph node involvement following resection of primary breast cancer.
- for the treatment of: acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, Non-Hodgkin lymphoma, metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcomas, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, metastatic bronchogenic carcinoma.

It is best practice to code the most specific ICD-10-CM Code within the indication to justify medical necessity, as documented in the medical record. Check payer policies as guidelines vary.

ICD-10-CM Diagnosis Coding

International Classification of Disease, 10th Edition, Clinical Modification Codes for OXDERYS Injection[14]

Indication	ICD-10-CM Codes
Acute Lymphoblastic Leukemia	C91.00, C91.02
Acute Myeloblastic Leukemia	C92.00, C92.02
Bladder Cancer	C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.7, C67.8, C67.9
Breast Cancer	C50.011 - C50.019, C50.021 - C50.029, C50.111 - C50.119, C50.121 - C50.129, C50.211 - C50.219, C50.221 - C50.229, C50.311 - C50.319, C50.321 - C50.329, C50.411 - C50.419, C50.421 - C50.429 C50.511 - C50.519, C50.521 - C50.529, C50.611 - C50.619, C50.621 - C50.629, C50.811 - C50.819, C50.821 - C50.829, C50.911 - C50.919, C50.921 - C50.929, C50.A0 - C50.A2
Bronchogenic Carcinoma	C34.00 - C34.02, C34.10 - C34.12, C34.2, C34.30 - C34.32, C34.80 - C34.82, C34.90 - C34.92
Gastric Cancer	C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C16.9
Hodgkin Lymphoma	C81.00 - C81.09, C81.10 - C81.19, C81.20 - C81.29, C81.30 - C81.39, C81.40 - C81.49, C81.90 - C81.99
Neuroblastoma	C30.0, C72.20 - C72.22, C74.10 - C74.12, C74.90 - C74.92
Non-Hodgkin Lymphoma	C82.00 - C82.09, C82.10 - C82.19, C82.20 - C82.29, C82.30 - C82.39, C82.40 - C82.49, C82.50 - C82.59, C82.60 - C82.69, C82.80 - C82.89, C82.90 - C82.99, C83.00 - C83.09, C83.10 - C83.19, C83.30 - C83.39, C83.50 - C83.59, C83.70 - C83.79, C83.80 - C83.89, C83.90 - C83.99, C84.00 - C84.09, C84.10 - C84.11, C84.40 - C84.49, C84.60 - C84.69, C84.A0 - C84.A9, C84.Z0 - C84.Z9, C84.90 - C84.99, C85.10 - C85.19, C85.20 - C85.29, C85.80 - C85.89, C85.90 - C85.99, C86.00, C86.10, C86.20, C86.30, C86.40, C86.50, C86.60, C88.00, C88.20, C88.30, C88.40, C88.80, C88.90
Osteosarcoma	C40.00 - C40.02, C40.10 - C40.12, C40.20 - C40.22, C40.30 - C40.32, C40.80 - C40.82, C40.90 - C40.92, C41.0, C41.1, C41.2, C41.3, C41.4, C41.9
Ovarian Cancer	C56.1, C56.2, C56.3, C56.9
Soft Tissue Sarcoma	C49.0, C49.10 - C49.12, C49.20 - C49.22, C49.3, C49.4, C49.5, C49.6, C49.8, C49.9
Thyroid Cancer	C73
Wilms' Tumor	C64.1, C64.2, C64.9
Encounter for Chemotherapy	Z51.11

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

ICD Diagnosis Codes by Indication

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

Acute Lymphoblastic Leukemia: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C91.00	Acute lymphoblastic leukemia, not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

Acute Myeloblastic Leukemia: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse

Bladder Cancer: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck; Malignant neoplasm of internal bladder orifice
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified

Breast Cancer: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C50.011 - C50.019	Malignant neoplasm of nipple and areola, female
C50.021 - C50.029	Malignant neoplasm of nipple and areola, male
C50.111 - C50.119	Malignant neoplasm of central portion of breast, female
C50.121 - C50.129	Malignant neoplasm of central portion of breast, male
C50.211 - C50.219	Malignant neoplasm of upper-inner quadrant of breast, female
C50.221 - C50.229	Malignant neoplasm of upper-inner quadrant of breast, male
C50.311 - C50.319	Malignant neoplasm of lower-inner quadrant of breast, female
C50.321 - C50.329	Malignant neoplasm of lower-inner quadrant of breast, male
C50.411 - C50.419	Malignant neoplasm of upper-outer quadrant of breast, female
C50.421 - C50.429	Malignant neoplasm of upper-outer quadrant of breast, male
C50.511 - C50.519	Malignant neoplasm of lower-outer quadrant of breast, female
C50.521 - C50.529	Malignant neoplasm of lower-outer quadrant of breast, male
C50.611 - C50.619	Malignant neoplasm of axillary tail of breast, female
C50.621 - C50.629	Malignant neoplasm of axillary tail of breast, male
C50.811 - C50.819	Malignant neoplasm of overlapping sites of breast, female
C50.821 - C50.829	Malignant neoplasm of overlapping sites of breast, male
C50.911 - C50.919	Malignant neoplasm of breast of unspecified site, female
C50.921 - C50.929	Malignant neoplasm of breast of unspecified site, male
C50.A0 - C50.A2	Malignant inflammatory neoplasm of breast

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Bronchogenic Carcinoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C34.00 - C34.02	Malignant neoplasm of main bronchus
C34.10 - C34.12	Malignant neoplasm of upper lobe, bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30 - C34.32	Malignant neoplasm of lower lobe, bronchus or lung
C34.80 - C34.82	Malignant neoplasm of overlapping sites of bronchus and lung
C34.90 - C34.92	Malignant neoplasm of unspecified part of bronchus or lung

Gastric Cancer: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified

Hodgkin Lymphoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C81.00-C81.09	Nodular lymphocyte predominant Hodgkin lymphoma
C81.10-C81.19	Nodular sclerosis Hodgkin lymphoma
C81.20-C81.29	Mixed cellularity Hodgkin lymphoma
C81.30-C81.39	Lymphocyte depleted Hodgkin lymphoma
C81.40-C81.49	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.90-C81.99	Hodgkin lymphoma

Neuroblastoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C30.0	Malignant neoplasm of nasal cavity
C72.20-C72.22	Malignant neoplasm of olfactory nerve
C74.00-C74.02	Malignant neoplasm of cortex of adrenal gland
C74.10-C74.12	Malignant neoplasm of medulla of adrenal gland
C74.90-C74.92	Malignant neoplasm of unspecified part of adrenal gland

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Non-Hodgkin Lymphoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C82.00-C82.09	Follicular lymphoma grade I
C82.10-C82.19	Follicular lymphoma grade II
C82.20-C82.29	Follicular lymphoma grade III, unspecified
C82.30-C82.39	Follicular lymphoma grade IIIa
C82.40-C82.49	Follicular lymphoma grade IIIb
C82.50-C82.59	Diffuse follicle center lymphoma
C82.60-C82.69	Cutaneous follicle center lymphoma
C82.80-C82.89	Other types of follicular lymphoma
C82.90-C82.99	Follicular lymphoma, unspecified
C83.00-C83.09	Small cell B-cell lymphoma
C83.10-C83.19	Mantle cell lymphoma
C83.30-C83.39	Diffuse large B-cell lymphoma
C83.50-C83.59	Lymphoblastic (diffuse) lymphoma
C83.70-C83.79	Burkitt lymphoma
C83.80-C83.89	Other non-follicular lymphoma
C83.90-C83.99	Non-follicular (diffuse) lymphoma, unspecified
C84.00-C84.09	Mycosis fungoides
C84.10-C84.11	Sézary disease
C84.40-C84.49	Peripheral T-cell lymphoma, not elsewhere classified
C84.60-C84.69	Anaplastic large cell lymphoma, ALK-positive
C84.A0-C84.A9	Cutaneous T-cell lymphoma
C84.Z0-C84.Z9	Other mature T/NK-cell lymphomas

Non-Hodgkin Lymphoma: ICD-10-CM Diagnosis Coding[14] (continued)

ICD-10 Code	Descriptor
C84.90-C84.99	Mature T/NK-cell lymphomas
C85.10-C85.19	Unspecified B-cell lymphoma
C85.20-C85.99	Mediastinal (thymic) large B-cell lymphoma
C85.80-C85.89	Other specified types of non-Hodgkin lymphoma
C85.90-C85.99	Non-Hodgkin lymphoma, unspecified
C86.00	Extranodal NK/T-cell lymphoma, nasal type not having achieved remission
C86.10	Hepatosplenic T-cell lymphoma not having achieved remission
C86.20	Enteropathy-type (intestinal) T-cell lymphoma not having achieved remission
C86.30	Subcutaneous panniculitis-like T-cell lymphoma not having achieved remission
C86.40	Blastic NK-cell lymphoma not having achieved remission
C86.50	Angioimmunoblastic T-cell lymphoma not having achieved remission
C86.60	Primary cutaneous CD30-positive T-cell proliferations not having achieved remission
C88.00	Waldenström macroglobulinemia not having achieved remission Osteosarcoma: ICD-10-CM Diagnosis Coding
C88.20	Heavy chain disease not having achieved remission
C88.30	Immunoproliferative small intestinal disease not having achieved remission
C88.40	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma] Lymphoma of skin-associated lymphoid tissue [SALT-lymphoma} Lymphoma of bronchial-associated lymphoid tissue [BALT-lymphoma]
C88.80	Other malignant immunoproliferative diseases not having achieved remission
C88.90	Malignant immunoproliferative disease, unspecified not having achieved remission

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Osteosarcoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C40.00-C40.02	Malignant neoplasm of scapula and long bones of upper limb
C40.10-C40.12	Malignant neoplasm of short bones of upper limb
C40.20-C40.22	Malignant neoplasm of long bones of lower limb
C40.30-C40.32	Malignant neoplasm of short bones of lower limb
C40.80-C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of limb
C40.90-C40.92	Malignant neoplasm of unspecified bones and articular cartilage of limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum, and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified

Ovarian Cancer: ICD-10-CM Diagnosis Coding[14]

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

Soft Tissue Sarcoma: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10-C49.12	Malignant neoplasm of connective and soft tissue of upper limb, including shoulder
C49.20-C49.22	Malignant neoplasm of connective and soft tissue of lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified

Thyroid Cancer: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
C73	Malignant neoplasm of thyroid gland

Wilms' Tumor: ICD-10-CM Diagnosis Coding[14]

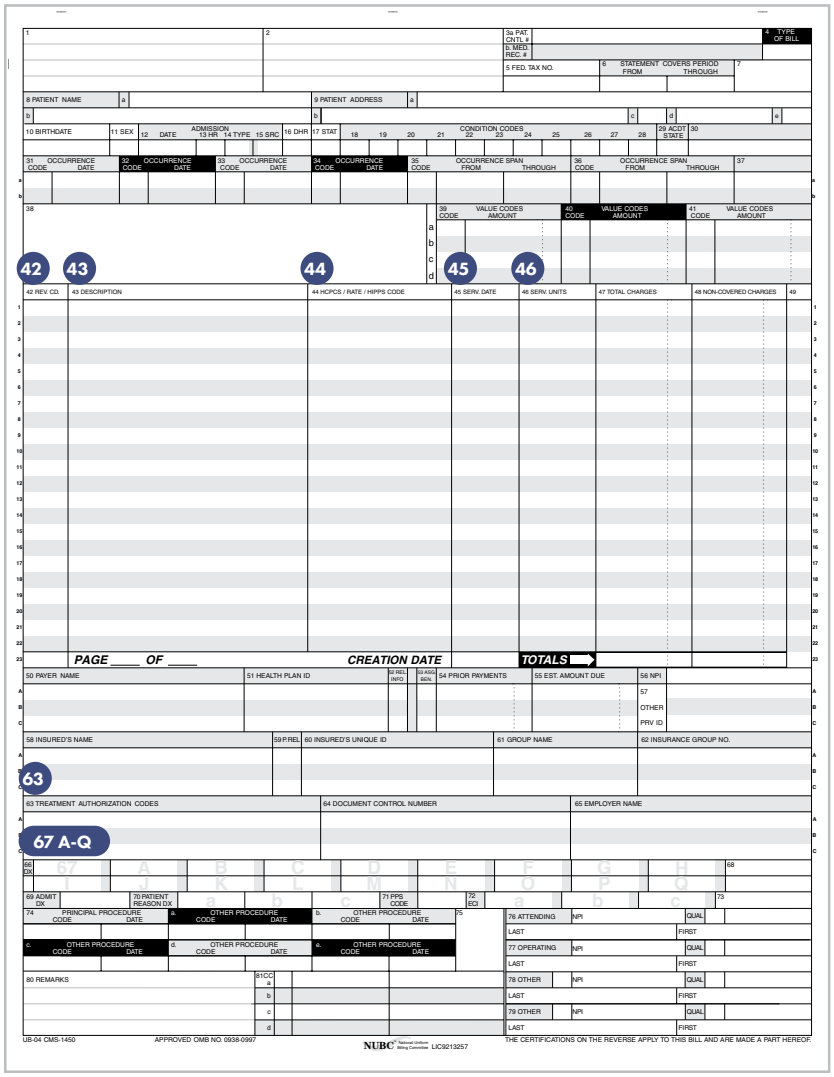
ICD-10 Code	Descriptor
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding[14]

ICD-10 Code	Descriptor
Z51.11	Encounter for antineoplastic chemotherapy

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

Sample Claim Form CMS-1450 (UB-04)[4,11-15]



Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/ files/EDI_837I_v5010A2_ crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf

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Form Locator (FL) 42

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

List the appropriate revenue code for the drug. Match the descriptor for OXDERYS Injection to your revenue code, 0636-Drugs requiring detailed coding.

Additionally, enter an appropriate revenue code for the administration service, such as 0335 - 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, submit the N4 indicator first, followed by the 11-digit NDC code. Then report the NDC unit of measure code, followed by the quantity. The NDC unit of measure code for OXDERYS is ML (milliliters).

FL 44 (Electronic Claim Form = Loop 2400, SV202-2) (SV202-1=HC/HP):

Enter the appropriate HCPCS code: ***J9999, Not otherwise classified antineoplastic drug***

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

OXDERYS dose, frequency, and cycle vary by the specific regimen administered. See package insert.

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

For drugs with no assigned J-Code, the service unit is 1. Check with individual payers regarding guidelines for service units.

FL 63 (Electronic Claim Form = Loop 2300, REF/G1/02):

Enter treatment authorization code.

FL 67 A-Q (Electronic Claim Form = Loop 2300, HI01-2) (HI01-1=BK):

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

An example for OXDERYS is: ***C91.00 Acute lymphoblastic leukemia, not having achieved remission.***

Use FL 67 C-L fields for other secondary diagnoses.

Sample Claim Form CMS-1500[4,5,11,13,14,16]

Item 19 (Electronic Claim Form = Loop 2400, Segment SV101-2)

Additional claim information:

When billing a not otherwise classified or unclassified J-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 here. Use Item 21 C-L fields for other secondary diagnoses.

Item 21 (Electronic Claim Form = Loop 2300, Segment HI01-2 through HI12-2):

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

An example for OXDERYS is: ***C91.00 Acute lymphoblastic leukemia, not having achieved remission.***

Use Item 21 C-L fields for other secondary diagnoses.

Item 23 (Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Item 24 A-B (Electronic Claim Form):

Item 24 A (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 red shaded portion, submit the N4 indicator first, followed by the 11-digit NDC code. Then, report the NDC unit of measure code followed by the quantity in the same red shaded portion. The NDC unit of measure code for OXDERYS is ML (milliliters).

Item 24 D (Electronic Claim Form = Loop 2400, Segment SV101):

J9999 Not otherwise classified antineoplastic drug

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

OXDERYS dose, frequency, and cycle vary by the specific regimen administered. See package insert.

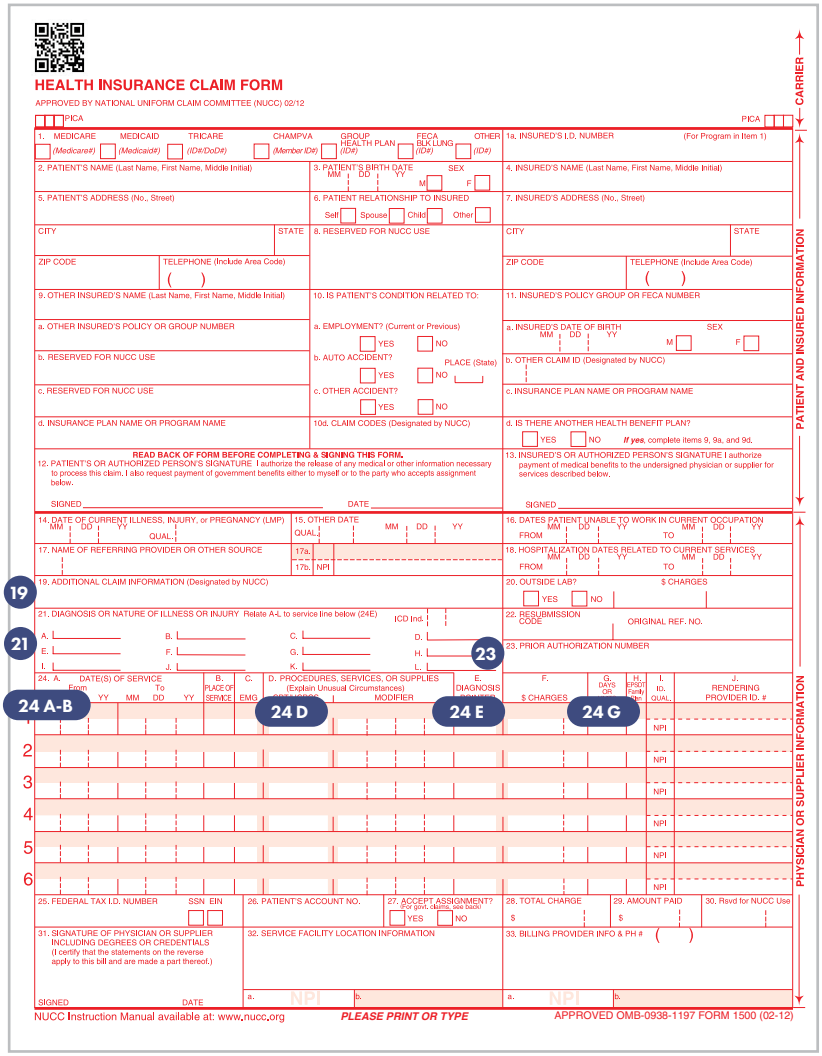
Item 24 E (Electronic Claim Form = Loop 2400, Segment SV107):

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

Item 24 G (Electronic Claim Form = Loop 2400, SV104):

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

For drugs with no assigned J-Code, the service unit is 1. Check with individual payers regarding guidelines for service units.



Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/ files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf

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Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

IMPORTANT SAFETY INFORMATION (continued)

Secondary Malignancies

The risk of developing secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) is increased following treatment with OXDERYS. Cumulative incidences ranged from 0.2% at five years to 1.5% at 10 years in two separate trials involving the adjuvant treatment of women with breast cancer. These leukemias generally occur within 1 to 3 years of treatment.

Extravasation and Tissue Necrosis

Extravasation of OXDERYS can cause severe local tissue injury manifesting as blistering, ulceration, and necrosis requiring wide excision of the affected area and skin grafting.

Extravasation should be considered if a patient experiences a burning or stinging sensation or shows other evidence indicating peri-venous infiltration or extravasation; however, extravasation may be present in patients who do not experience a stinging or burning sensation or when blood return is present on aspiration of the infusion needle.

When given via a peripheral venous line, infuse OXDERYS over 10 minutes or less to minimize the risk of thrombosis or perivenous extravasation.

If extravasation is suspected, immediately discontinue the intravenous injection or continuous intravenous infusion. Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. In adults, if appropriate, administer dexrazoxane at the site of extravasation as soon as possible and within the first 6 hours after extravasation.

Severe Myelosuppression

OXDERYS can cause myelosuppression. In Study 1, the incidence of severe myelosuppression was: grade 4 leukopenia (0.3%), grade 3 leukopenia (3%), and grade 4 thrombocytopenia (0.1%). A dose-dependent, reversible neutropenia is the predominant manifestation of myelosuppression from doxorubicin hydrochloride. When OXDERYS is administered every 21 days, the neutrophil count reaches its nadir 10 to 14 days after administration with recovery usually occurring by day 21.

Obtain complete blood counts prior to each treatment and carefully monitor patients during treatment for possible clinical complications due to myelosuppression. Delay next dose of OXDERYS if severe myelosuppression has not improved. Consider dose reduction for patients with prolonged myelosuppression based on severity of reaction.

Tumor Lysis Syndrome

OXDERYS can induce tumor lysis syndrome in patients with rapidly growing tumors. Evaluate blood uric acid levels, potassium, calcium, phosphate, and creatinine after initial treatment. Hydration, urine alkalinization, and prophylaxis with allopurinol to prevent hyperuricemia may minimize potential complications of tumor lysis syndrome.

Potentiation of Radiation Toxicity and Radiation Recall

OXDERYS can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive OXDERYS after prior radiation therapy.

Embryo-Fetal Toxicity

OXDERYS can cause fetal harm when administered to a pregnant woman; avoid the use of OXDERYS during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin hydrochloride during the 2nd and 3rd trimesters. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OXDERYS and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with OXDERYS and for 3 months after the last dose. Advise males with pregnant partners to use condoms during treatment with OXDERYS and for at least 10 days after the last dose.

ADVERSE REACTIONS

The most common (>10%) adverse reactions are alopecia, nausea and vomiting.

DRUG INTERACTIONS

Effect of Other Drugs on OXDERYS

Inhibitors of CYP3A4, CYP2D6, and P-gp

- Avoid concomitant use of OXDERYS with inhibitors of CYP3A4, CYP2D6, or P-gp. Concomitant use of doxorubicin hydrochloride with inhibitors of CYP3A4, CYP2D6, or P- glycoprotein (P-gp), increased concentrations of doxorubicin, which may increase the incidence and severity of adverse reactions of OXDERYS.

Inducers of CYP3A4, CYP2D6, or P-gp

- Avoid concomitant use of OXDERYS with inducers of CYP3A4, CYP2D6, or P-gp. Concomitant use of doxorubicin hydrochloride with inducers of CYP3A4, CYP2D6, or P-gp may decrease the concentration of doxorubicin.

Paclitaxel

- Administer OXDERYS prior to paclitaxel if used concomitantly. Paclitaxel, when given prior to doxorubicin hydrochloride, increases the plasma concentrations of doxorubicin and its metabolites.

Concomitant Use of Trastuzumab

Avoid concomitant administration of OXDERYS and trastuzumab. Concomitant use of trastuzumab and doxorubicin hydrochloride results in an increased risk of cardiac dysfunction.

Patients receiving doxorubicin after stopping treatment with trastuzumab may also be at an increased risk of developing cardiotoxicity. Trastuzumab may persist in the circulation for up to 7 months. Therefore, avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab when possible. If anthracyclines are used before this time, carefully monitor cardiac function.

Concomitant Use of Dexrazoxane

Do not administer dexrazoxane as a cardioprotectant at the initiation of OXDERYS-containing chemotherapy regimens.

Concomitant Use of 6-Mercaptopurine

OXDERYS may potentiate 6-mercaptopurine-induced hepatotoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Doxorubicin hydrochloride injection can cause fetal harm when administered to a pregnant woman. Avoid the use of OXDERYS during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use

IMPORTANT SAFETY INFORMATION (continued)

of doxorubicin hydrochloride during the 2nd and 3rd trimesters. Advise pregnant women of the potential risk to a fetus.

Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with OXDERYS and for 10 days after the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating OXDERYS.

Contraception

OXDERYS can cause fetal harm when administered to pregnant women. Advise female patients of reproductive potential to use effective contraception during treatment with OXDERYS and for 6 months after the last dose.

OXDERYS may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Due to the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with OXDERYS and for 3 months after the last dose. Males with pregnant partners should use condoms during treatment and for at least 10 days after the last dose.

Infertility

In females of reproductive potential, OXDERYS may cause infertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment.

OXDERYS may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men. This may occur several years after the end of therapy.

Pediatric Use

Based on postmarketing reports, pediatric patients treated with doxorubicin hydrochloride are at risk for developing late cardiovascular dysfunction. Risk factors include young age at treatment (especially < 5 years), high cumulative doses and receipt of combined modality therapy. Long-term periodic cardiovascular monitoring is recommended for all pediatric patients who have received doxorubicin hydrochloride. OXDERYS, as a component of intensive chemotherapy regimens administered to pediatric patients, may contribute to prepubertal growth failure and may also contribute to gonadal impairment, which is usually temporary.

There are no recommended dose adjustments based on age. Doxorubicin clearance was increased in patients aged 2 years to 20 years as compared to adults, while doxorubicin clearance was similar in infants less than 2 years as compared to adults.

Geriatric Use

Clinical experience in patients who were 65 years of age and older who received doxorubicin hydrochloride-based chemotherapy regimens for metastatic breast cancer showed no overall differences in safety and effectiveness compared with younger patients.

Hepatic Impairment

The clearance of doxorubicin was reduced in patients with elevated serum total bilirubin levels. OXDERYS is contraindicated in patients with severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin levels greater than 5 mg/dL). Reduce the dose of OXDERYS in patients with serum total bilirubin levels greater than 1.2 mg/dL.

DOSAGE AND ADMINISTRATION

OXDERYS is a hazardous drug. Follow applicable special handling and disposal procedures.

Decrease the rate of infusion if erythematous streaking along the vein proximal to the site of infusion or facial flushing occur.

Management of Suspected Extravasation

Immediately discontinue OXDERYS for burning or stinging sensation or other evidence indicating peri-venous infiltration or extravasation. Manage confirmed or suspected extravasation as follows:

- Do not remove the needle until attempts are made to aspirate extravasated fluid.
- Do not flush the line.
- Avoid applying pressure to the site.
- Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days.
- If the extravasation is in an extremity, elevate the extremity.
- In adults, consider administration of dexrazoxane.

Management of Contact with Skin or Eyes

Treat accidental contact with the skin or eyes immediately by copious lavage with water, or soap and water, or sodium bicarbonate solution. Do not abrade the skin by using a scrub brush. Seek medical attention.

Incompatibility with Other Drugs

Do not admix OXDERYS with other drugs. If OXDERYS is mixed with heparin or fluorouracil, a precipitate may form. Avoid contact with alkaline solutions which can lead to hydrolysis of doxorubicin hydrochloride.

Please see OXDERYS full Prescribing Information, including BOXED WARNING.

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.

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OXDERYS™
(doxorubicin hydrochloride injection)



40 mg/20 mL (2 mg/mL)
NDC: 83831-0161-20



160 mg/80 mL (2 mg/mL)
NDC: 83831-0162-80

AVYXA Pharma, LLC offers resources to help your patients start and stay on prescribed therapy. We are dedicated to providing your patients with ongoing support to help them access AVYXA Pharma, LLC medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

Please see Important Safety Information including **Boxed Warning**, on pages 3, 21 and 22 and full Prescribing Information for OXDERYS.

AVYXA

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US-OXD-0004-1 I November 2026