



DOXILine® call (800) 609-1083 Monday-Friday 8 AM - 8 PM ET Fax: (800) 987-5572

HOME	BILLING	PATIENT ACCESS	PRESCRIBING INFORMATION, INCLUDING BOXED WARNINGS	KEY LINKS	HELPFUL RESOURCES
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DOXIL® Reimbursement - Overview
Toolkit
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• Printable Version
Treatment Notes / Flow Sheet
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DOXIL® (doxorubicin HCl liposome injection) Full Prescribing Info
Online Reimbursement & Health Care Resources

▼ RESOURCES

Toolkit

Evaluation & Management Progress Note

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EM PROGRESS NOTE/ Dictation Format (1995 EM Guidelines)	
Patient Name:	Date of Service:
Vital Signs: P = T = R = BP = Weight =	
Appearance:	
Chief Complaint(s) today:	
CC status: Stable Improving Unimproved Deteriorating	
Secondary Problems:	
History of Present Illness:	
Past History:	Family History:
Social History:	
Review of Systems (History):	Physical Exam (Physical):
Constitutional:	Constitutional:
Eyes:	Eyes:
ENT:	ENT:
CV:	CV:
Respiratory:	Respiratory:
GI:	GI:
GU:	GU:
Musculoskeletal:	Musculoskeletal:

Integumentary:	Integumentary:
Neuro:	Neuro:
Psych:	Psych:
Endocrine:	Endocrine:
Hematologic/ Lymphatic:	Hematologic/ Lymphatic:
Allergy/ Immunological:	Allergy/ Immunological:
All Others Non-Contributory:	All Others Non-Contributory:
MEDICAL DECISION-MAKING	Body Areas:
Data Reviewed Today:	Head:
	Face:
	Neck:
Tests To Order:	Chest:
	Abdomen:
	Genitalia:
	Back:
Diagnoses, Drugs and/or Procedures Considered:	Extremities:
	Counseling:
Drugs and/or Procedures Ordered:	Reason:
	Time of Counseling:
	Total Visit Time:
	Nursing Supervision:

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▼ **INDICATIONS AND IMPORTANT SAFETY INFORMATION**

Indications for DOXIL® (doxorubicin HCl liposome injection)

- DOXIL® (doxorubicin HCl liposome injection) is indicated for the treatment of patients with ovarian cancer whose disease has progressed or recurred after prior platinum-based therapy
- DOXIL® in combination with VELCADE® (bortezomib) is indicated for the treatment of patients with multiple myeloma who have not previously received VELCADE® and have received at least one prior

- therapy
- DOXIL® is indicated for the treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy

Important Safety Information for DOXIL® (doxorubicin HCl liposome injection)

BOXED WARNINGS:

Cardiotoxicity, infusion reaction, myelosuppression, liver impairment, substitution

- **The use of DOXIL® may lead to cardiac toxicity. Myocardial damage may lead to congestive heart failure and may occur as the total cumulative dose of doxorubicin HCl approaches 550mg/m²**
 - **Prior use of other anthracyclines or anthracenediones should be included in calculations of total cumulative dose**
 - **Cardiac toxicity may also occur at lower cumulative doses (400 mg/m²) in patients with prior mediastinal irradiation or who are receiving concurrent cyclophosphamide therapy**
- **Acute infusion-related reactions including, but not limited to, flushing, shortness of breath, facial swelling, headache, chills, back pain, tightness in the chest or throat, and/or hypotension have occurred in up to 10% of patients treated with DOXIL®. In most patients, these reactions have resolved within several hours to a day once the infusion is terminated. In some patients, reactions resolved with slowing of the infusion rate**
 - **Serious and sometimes life-threatening or fatal allergic/anaphylactoid-like infusion reactions have occurred. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use**
 - **The initial rate of infusion should be 1mg/min to minimize the risk of infusion reactions**
- **Severe myelosuppression may occur**
- **DOXIL® dosage should be reduced in patients with impaired hepatic function**
- **Accidental substitution has resulted in severe side effects. Do not substitute for doxorubicin HCl on a mg per mg basis.**

Contraindications

- Patients with a history of hypersensitivity reactions to a conventional doxorubicin formulation or the components of DOXIL®
- Nursing mothers

Additional Safety Information

- Cardiac function should be carefully monitored
 - Congestive heart failure or cardiomyopathy may occur after discontinuation of anthracycline therapy
 - For patients with a history of cardiovascular disease, or if the results of cardiac monitoring indicate possible cardiac injury, the benefit of therapy must be weighed against the risk of myocardial injury
 - In the randomized multiple myeloma study, 25 patients (8%) in the VELCADE® for Injection arm and 42 patients (13%) in the VELCADE® plus DOXIL® arm experienced left ventricular ejection fraction decrease (defined as absolute decrease \geq 15% over baseline or a \geq 5% decrease below institutional lower limit of normal)
- Myelosuppression may occur; frequently monitor complete blood count (including platelet count), at least prior to each dose of DOXIL®
 - In patients with recurrent ovarian cancer or AIDS-related Kaposi's sarcoma, hematologic toxicity (based on platelet count or absolute neutrophil count) may require dose reduction or delay in administration of DOXIL®
 - In patients with multiple myeloma, hematologic toxicity (based on platelet count, absolute neutrophil count, hemoglobin level, or neutropenia with fever) may require dose reduction, delay in administration, or suspension of DOXIL® and/or VELCADE®
 - Persistent severe myelosuppression may result in superinfection, neutropenic fever, or hemorrhage
 - Sepsis occurring during neutropenia has resulted in discontinuation of treatment and in rare cases of death
- DOXIL® may potentiate the toxicity of other anticancer therapies, especially hematologic toxicities, when used in combination with other therapies that suppress bone marrow
- Hand-foot syndrome (HFS) may occur during therapy with DOXIL®
 - Based on HFS toxicity grade, dose reduction, delay in administration, or discontinuation of DOXIL® may be required
 - HFS was generally observed after 2 to 3 cycles of treatment, but may occur earlier
 - The reaction was mild in most patients, resolving in 1 to 2 weeks
 - The reaction can be severe and debilitating in some patients, resulting in discontinuation of therapy
- DOXIL® is an irritant, not a vesicant; use precautions to avoid extravasation
- DOXIL® can cause fetal harm when used during pregnancy
- Recall reaction has occurred with DOXIL® administration after radiotherapy

DOXIL may interact with drugs known to interact with the conventional formulation of doxorubicin HCl

- In patients with recurrent ovarian cancer, the most common all-grade adverse reactions (ARs) \geq 20% (DOXIL[®] vs topotecan, respectively) included: asthenia (40% vs 51%), fever (21% vs 31%), nausea (46% vs 63%), stomatitis (41% vs 15%), vomiting (33% vs 44%), diarrhea (21% vs 35%), anorexia (20% vs 22%), dyspnea (15% vs 23%), HFS (51% vs 1%), and rash (29% vs 12%)
 - In addition, 19% vs 52.3% reported alopecia (all grades)
 - Grade 3/4 hematologic ARs reported in \geq 5% (DOXIL[®] vs topotecan, respectively) were neutropenia (12% vs 76%) and anemia (6% vs 29%)
- In patients with multiple myeloma, the most common all-grade ARs \geq 20% (VELCADE[®] plus DOXIL[®] vs VELCADE[®], respectively) included: neutropenia (36% vs 22%), thrombocytopenia (33% vs 28%), anemia (25% vs 21%), fatigue (36% vs 28%), pyrexia (31% vs 22%), asthenia (22% vs 18%), nausea (48% vs 40%), diarrhea (46% vs 39%), vomiting (32% vs 22%), constipation (31% vs 31%), mucositis/stomatitis (20% vs 5%), peripheral neuropathy (42% vs 45%), neuralgia (17% vs 20%), and rash (22% vs 18%)
 - In addition, 19% vs < 1% reported HFS
- In patients with AIDS-related Kaposi's sarcoma, ARs reported in \geq 5% of DOXIL[®]-treated patients were: neutropenia (ANC < 1000/mm³, 46%; < 500/mm³, 11%), anemia (Hb < 10 g/dL, 58%; < 8 g/dL, 16%), thrombocytopenia (< 150,000 platelets/mm³, 61%), nausea (18%), asthenia (7%), fever (8%), alopecia (9%), vomiting (8%), diarrhea (5%), and stomatitis (5%)

Please click here for DOXIL[®] full [Prescribing Information](#), including **Boxed WARNINGS.**

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