



DOXILine™ call (800) 609-1083

Monday–Friday 9:00 AM–8:00 PM E.T. Fax: (800) 987-5572

- HOME
- BILLING
- PATIENT ASSISTANCE
- PRESCRIBING INFORMATION, INCLUDING BOXED WARNINGS
- KEY LINKS
- HELPFUL RESOURCES

Introduction

DOXIL Reimbursement - Overview

Toolkit

[Evaluation & Management Progress Note](#)

• [Printable Version](#)

[Treatment Notes / Flow Sheet](#)

• [Printable Version](#)

DOXIL® (doxorubicin HCl liposome injection) Full Prescribing Info

Online Reimbursement & Health Care Resources

▼ RESOURCES

Toolkit

Chemotherapy Treatment Notes/Flow Sheet

The information contained in this document is provided for information purposes only and represents no statement, promise or guarantee by Centocor Ortho Biotech Inc. concerning levels of reimbursement, payment, or charge. We strongly suggest that you consult your payor organization with regard to local reimbursement policies.

Chemotherapy Treatment Notes

Patient Name: _____ **Pt. Acct #** _____ **M.D.** _____

Date: ___/___/___ Pre Rx Laboratories Checked Redness, Swelling or Discomfort at site

Yes(explain below) No

IV Administration: Peripheral Port Hickman Groshong PICC
 Other _____

Blood Return: Present Not Present (explain below) Left Right
Port Flushed per Protocol _____

Butterfly Cannula Huber/Gripper Needle Site _____ Dorsal Plantar

Drug or Treatment	Dose	Reconstituted	IV Solution	Solution Size	Route	Time On	Time Off	Notes
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250	PO IM IVP IV IA PUMP			

				500 / 1000	INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			

Notes:

M.D. On Site

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Date: ___/___/___ Pre Rx Laboratories Checked Redness, Swelling or Discomfort at site
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 Plantar

Drug or Treatment	Dose	Reconstituted	IV Solution	Solution Size	Route	Time On	Time Off	Notes
		With _____ _____ Amt. _____		50 / 100 150 / 250	PO IM IVP IV IA			

				500 / 1000	PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
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		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			
		With _____ _____ Amt. _____		50 / 100 150 / 250 500 / 1000	PO IM IVP IV IA PUMP INTRA			

Notes:

M.D. On Site

Indications:

- 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

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
 - o 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
 - o Based on HFS toxicity grade, dose reduction, delay in administration, or discontinuation of DOXIL may be required
 - o 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%)
 - o In addition, 19% vs 52.3% reported alopecia (all grades).
 - o 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%)
 - o 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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