VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Blenoxane (bleomycin)

Effective Date: 10/22/13

Date Developed: 9/3/13 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Pharmacologic Category: Antineoplastic Agent, Antibiotic. Bleomycin binds to DNA leading to single- and double-strand breaks. To a lesser degree it inhibits RNA and protein synthesis.

Preauthorization Criteria:

Treatment of squamous cell carcinomas of the head and neck; Hodgkin's lymphoma; testicular cancer; sclerosing agent for malignant pleural effusion

Off Label: Germ cell tumors, malignant; Gestational trophoblastic neoplasia, high-risk, refractory

Dosing: Consult product information for specific dosing regimens

Intrapleural: 60 units in 50-100 mL NS; use of topical anesthetics or opioid analgesia is usually not necessary

C a u t i o n :

I.V. doses should be administered slowly over 10 minutes.

I.M. or SubQ: May cause pain at injection site

Major Adverse Reactions and Black Box Warnings:

>10%:

Dermatologic: Pain at the tumor site, phlebitis. About 50% of patients develop erythema, rash, striae, induration, hyperkeratosis, vesiculation, and peeling of the skin, particularly on the palmar and plantar surfaces of the hands and feet. Hyperpigmentation (50%), alopecia, nailbed changes may also occur. These effects appear dose related and reversible with discontinuation.

Gastrointestinal: Stomatitis and mucositis (30%), anorexia, weight loss

Respiratory: Tachypnea, rales, acute or chronic interstitial pneumonitis, and pulmonary fibrosis (5% to 10%); hypoxia and death (1%).

Miscellaneous: Acute febrile reactions (25% to 50%)

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Contraindications

Hypersensitivity to bleomycin or any component of the formulation

BOXED WARNINGS:

- **Idiosyncratic reaction**: **A severe idiosyncratic reaction consisting of hypotension, mental confusion, fever, chills, and wheezing (similar to anaphylaxis) has been reported in 1% of lymphoma patients treated with bleomycin.** *Since these reactions usually occur after the first or second dose, careful monitoring is essential after these doses*.
- **Pulmonary toxicity**: **Occurrence of pulmonary fibrosis (commonly presenting as pneumonitis; occasionally progressing to pulmonary fibrosis) is the most severe toxicity. Risk is higher in elderly patients or patients receiving >400 units total lifetime dose;** other possible risk factors include smoking and patients with prior radiation therapy or receiving concurrent oxygen (especially high inspired oxygen dose)

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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