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

Pharmacologic Category: Antineoplastic Agent, Antibiotic

Preauthorization Criteria:

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

Dosing: Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Administration:

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

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

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

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%). Symptoms include cough, dyspnea, and bilateral pulmonary infiltrates. The pathogenesis is not certain, but may be due to damage of pulmonary, vascular, or connective tissue. Response to steroid therapy is variable and somewhat controversial.

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

1% to 10%:

Dermatologic: Skin thickening, diffuse scleroderma, onycholysis, pruritus

Miscellaneous: Anaphylactoid-like reactions (characterized by hypotension, confusion, fever, chills, and wheezing; onset may be immediate or delayed for several hours); idiosyncratic reactions (1% in lymphoma patients)

<1% (Limited to important or life-threatening): Angioedema, cerebrovascular accident, cerebral arteritis, chest pain, coronary artery disease, flagellate hyperpigmentation, hepatotoxicity, malaise, MI, myelosuppression (rare), myocardial ischemia, nausea, pericarditis, Raynaud's phenomenon, renal toxicity, scleroderma-like skin changes, Stevens-Johnson syndrome, thrombotic microangiopathy, toxic epidermal necrolysis, vomiting

Contraindications

Hypersensitivity to bleomycin or any component of the formulation

- Idiosyncratic reaction: **[U.S. Boxed Warning]: 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: **[U.S. Boxed Warning]: 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 doses). A review of patients receiving bleomycin for the treatment of germ cell tumors suggests risk for pulmonary toxicity is increased in patients >40 years of age, with glomerular filtration rate <80 mL/minute, advanced disease, and cumulative doses >300 units (O'Sullivan, 2003). Pulmonary toxicity may include bronchiolitis obliterans and organizing pneumonia (BOOP), eosinophilic hypersensitivity, and interstitial pneumonitis, progressing to pulmonary fibrosis (Sleijfer, 2001); pulmonary toxicity may be due to a lack of the enzyme which inactivates bleomycin (bleomycin hydrolase) in the lungs (Morgan, 2011; Sleijfer, 2001), If pulmonary changes occur, withhold treatment and investigate if drug-related.

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