VENTURA COUNTY
HEALTH CARE PLAN

Taxol (paclitaxel)

Effective Date: 10/22/13

Date Developed: 09/3/13 by Albert Reeves MD

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

Paclitaxel is a plant-derived mitotic-inhibiting antineoplastic agent used in cancer chemotherapy. Taxol can distort mitotic spindles, resulting in the breakage of chromosomes. Paclitaxel may also suppress cell proliferation and modulate immune response.

Pre-Authorization Criteria:

Breast cancer: Adjuvant treatment of node-positive breast cancer (as sequential therapy following anthracycline-containing combination chemotherapy); treatment of metastatic breast cancer after failure of combination chemotherapy (for metastatic disease) or relapse within 6 months of adjuvant chemotherapy (prior therapy should have included an anthracycline unless contraindicated).

Kaposi sarcoma, AIDS-related: Second-line treatment of AIDS-related Kaposi sarcoma.

Non-small cell lung cancer: First-line treatment of non-small cell lung cancer (in combination with cisplatin) in patients who are not candidates for potentially curative surgery and/or radiation therapy.

Ovarian cancer, advanced: Subsequent therapy for treatment of advanced ovarian cancer; first-line therapy of ovarian cancer (in combination with cisplatin).

Off-Label:

Anal cancer, advanced; Bladder cancer, advanced or metastatic; Cervical cancer, advanced; Endometrial cancer, advanced or recurrent; Esophageal cancer, metastatic or unresectable locally advanced; Esophageal/esophagogastric cancer, preoperative chemoradiation; Gastric cancer, metastatic or unresectable locally advanced; Gestational trophoblastic neoplasia, high-risk, refractory; Head and neck cancers, advanced; Melanoma, advanced or metastatic; Penile cancer, metastatic; Small cell lung cancer, relapsed/refractory; Soft tissue sarcoma, angiosarcoma, advanced or unresectable; Testicular germ cell tumors, relapsed/refractory; Thymoma/thymic carcinoma, advanced; Thyroid cancer, anaplastic;

Unknown primary adenocarcinoma

Adult Dosing (should be prescribed by an Oncologist):

NOTE: The manufacturers recommend premedication with dexamethasone (20 mg orally at 12 and 6 hours prior to paclitaxel [reduce dexamethasone dose to 10 mg orally with advanced HIV disease]), diphenhydramine (50 mg IV 30 to 60 minutes prior to paclitaxel), and cimetidine or famotidine (IV 30 to 60 minutes prior to paclitaxel).

Ovarian carcinoma:

I.V.: 135-175 mg/m^2 over 3 hours every 3 weeks **or** 135 mg/m^2 over 24 hours every 3 (in combination with cisplatin)

Metastatic breast cancer: I.V.: 175-250 mg/m^2 over 3 hours every 3 weeks

Breast cancer, adjuvant treatment: IV: 175 mg/m^2 over 3 hours every 3 weeks for 4 cycles (administer sequentially following an anthracycline-containing regimen).

Non-small cell lung carcinoma: I.V.: 135 mg/m^2 over 24 hours every 3 weeks (in combination with cisplatin)

AIDS-related Kaposi's sarcoma: I.V.: 135 mg/m^2 over 3 hours every 3 weeks
or 100 mg/m^2 over 3 hours every 2 weeks

ADVERSE REACTIONS: edema, alopecia, nausea and vomiting, diarrhea, stomatitis, bone marrow suppression, peripheral neuropathy

ALERT- US Boxed Warning:

Paclitaxel should be administered under the supervision of a health care provider experienced in the use of cancer chemotherapeutic agents. Anaphylaxis and severe hypersensitivity reactions have occurred in 2% to 4% of patients. Should not be given to patients with solid tumors who have baseline neutrophil counts of less than 1,500 cells/mm^3 or to patients with AIDS-related Kaposi sarcoma if the baseline neutrophil count is less than 1,000 cells/mm^3.

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DRUG INTERACTIONS: There are several potential drug interactions (e.g.other antineoplastic agents, clozapine, CYP2C8 AND CYP3A4 effects, numerous herbs, etc). Refer to product information for complete listing.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Modified preauthorization criteria and dosing section. Added Off Label and Adverse reaction information. Reference updated