Abraxane is a taxane plant derivative that interferes with cell division by inhibiting microtubular function.

Pre-authorization Criteria:

Treatment of refractory (metastatic) or relapsed (within 6 months of adjuvant therapy) breast cancer after failure of combination chemotherapy (including anthracycline-based therapy unless clinically contraindicated); first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) (in combination with carboplatin) in patients ineligible for curative surgery or radiation therapy; first-line treatment of patients with metastatic adenocarcinoma of the pancreas (in combination with gemcitabine).

Note: Off-label uses are not covered. These uses include treatment of recurrent or persistent ovarian, fallopian tube, or primary peritoneal cancers. See VCHCP policy for Coverage of Prescription Medications for Off-Label use for details.

Dosing:

Note: Methods of administration vary if combinations of medications are utilized. Refer to specific protocols.

Adult:

**Breast cancer, metastatic:** I.V.: 260 mg/m² every 3 weeks

**Non-small cell lung cancer (NSCLC), locally advanced or metastatic:** I.V.: 100 mg/m² on days 1, 8, and 15 of each 21-day cycle (in combination with carboplatin)

**Breast cancer (unlabeled dosing):** I.V.: 100-150 mg/m² on days 1, 8, and 15 of a 28-day cycle (Gradishar, 2009)
Ovarian, fallopian tube, or primary peritoneal cancer (recurrent; unlabeled use): I.V.: 260 mg/m² on day 1 of a 21-day cycle for 6-8 cycles (Teneriello, 2009) or 100 mg/m² on days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity (Coleman, 2011)

Pancreatic cancer, metastatic (unlabeled use): I.V.: 125 mg/m² on days 1, 8, and 15 of a 28-day cycle (in combination with gemcitabine) until disease progression or unacceptable toxicity (Von Hoff, 2011)

Dosing: Geriatric

Refer to adult dosing.

Dosing: Renal Impairment

No dosage adjustment provided in manufacturer’s labeling (has not been studied).

Dosing: Hepatic Impairment

Breast cancer (every 3 week regimen):

Mild impairment (AST <10 times ULN and bilirubin ≤1.25 times ULN): No adjustment required. Moderate impairment (AST <10 times ULN and bilirubin 1.26-2 times ULN): Reduce dose to 200 mg/m²

Severe impairment:

AST <10 times ULN and bilirubin 2.01-5 times ULN: Reduce dose to 130 mg/m²; may increase up to 200 mg/m² in subsequent cycles (based on individual tolerance)

AST >10 times ULN or bilirubin >5 times ULN: Use is not recommended

Non-small cell lung cancer (NSCLC) regimen:

Mild impairment (AST <10 times ULN and bilirubin ≤1.25 times ULN): No dosage adjustment necessary.

Moderate impairment (AST <10 times ULN and bilirubin 1.26-2 times ULN): Reduce dose to 75 mg/m²

Severe impairment:

AST <10 times ULN and bilirubin 2.01-5 times ULN: Reduce dose to 50 mg/m²; may increase up to 75 mg/m² in subsequent cycles (based on individual tolerance)

AST >10 times ULN or bilirubin >5 times ULN: Use is not recommended.

Administration:
I.V.: Administer over 30 minutes (limiting the infusion rate to 30 minutes reduces the risk for infusion-related reaction); do not use an in-line filter. Monitor infusion site; avoid extravasation. When given on a weekly (unlabeled) schedule, infusions were administered over ~30 minutes (Gradishar, 2009; Rizvi, 2008). When administered as part of a combination chemotherapy regimen, sequence of administration may vary by regimen; refer to specific protocol for sequence of administration.

Precautions:

Hazardous agent; use appropriate precautions for handling and disposal [NIOSH, 2012]. Black Box Warning: Neutropenia due to bone marrow suppression (do not use if baseline neutrophil count is less than 1500 cells/mm3); do not intermix with albumin form of paclitaxel; sensory neuropathy; hepatic impairment;

Drug Interactions: Paclitaxel metabolism is catalyzed by CYP2C8 and CYP3A4. Use caution if administered with medicines known to inhibit or induce these enzymes.

References:

11. Nyman DW, Campbell KJ, Hersh E, et al, “Phase I and Pharmacokinetics Trial of ABI-007, a Novel