### APPROVAL CRITERIA

Protein bound paclitaxel (Abraxane) (may be approved for the treatment of any of the following indications:

I. Relapsed or metastatic breast cancer when the following criteria are met (NCCN 2A):
   A. Used as a single agent; **AND**
   B. Used in a single line of therapy

   **OR**

   II. Treatment of any breast cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

   **OR**

   III. First-line treatment of metastatic or unresectable locally advanced triple negative breast cancer (lack of estrogen-and progesterone-receptor expression and no overexpression of HER2) when used in combination with atezolizumab (Tecentriq) are met (NCCN 2A);

   **OR**

   IV. Malignant Melanoma when the following criteria are met (NCCN 2A);
   A. Used as a single agent; **AND**
   B. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 following at least one prior therapy (Kottschade 2011);

   **OR**

   V. Treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) when the following criteria are met:
   A. Used as first-line therapy; **AND**
   B. Given in combination with carboplatin or cisplatin;

   **OR**

   VI. Treatment of locally advanced or metastatic squamous NSCLC when all of the following criteria are met (NCCN 1, NCCN 2A):
   A. Used as first-line therapy; **AND**
   B. Individual has a current ECOG performance status of 0-2; **AND**

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C. Given in combination with platinum-based therapy (carboplatin or cisplatin) and pembrolizumab;

OR

VII. Treatment of NSCLC in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

VIII. Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) when the following criteria are met (NCCN 2A):
   A. Treatment of persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer); OR
   B. Treatment of persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity;

OR

IX. Locally advanced or metastatic adenocarcinoma of the pancreas when the following criteria are met:
   A. Used as first-line therapy or later; AND
   B. Given in combination with gemcitabine as a single-line of therapy;

OR

X. Recurrent, metastatic, or high-risk endometrial cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XI. Solid tumors where treatment with a taxane is medically appropriate and the individual has confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A).

Abraxane (paclitaxel, protein-bound) may not be approved when the above criteria are not met and for all other indications.

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