Abraxane (paclitaxel, protein-bound)

**Override**

<table>
<thead>
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<th>Approval Duration</th>
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<td>Prior Authorization</td>
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**Medication**

| Abraxane (paclitaxel, protein-bound) |

**APPROVAL CRITERIA**

Requests for Abraxane (paclitaxel, protein-bound) 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. Metastatic or unresectable locally advanced breast cancer when the following criteria are met (NCCN 2A):
   A. Individual has triple-negative breast cancer, defined as lack of estrogen- and progesterone-receptor expression and no overexpression of HER2; **AND**
   B. Using as first line treatment; **AND**
   C. Individual is using in combination with atezolizumab;

OR

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

OR

IV. Malignant Melanoma when the following criteria are met (NCCN 2A):
   A. Used as a single agent; **AND**
   B. Individual is using as second line or subsequent therapy; **AND**
   C. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 (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

VI. Treatment of locally advanced or metastatic squamous NSCLC when all of the following criteria are met (NCCN 1, NCCN 2A):

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
### Market Applicability

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<tr>
<th>Market</th>
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<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
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A. Used as first-line therapy; **AND**
B. Given in combination with carboplatin and pembrolizumab; **AND**
C. Individual has a current ECOG performance status of 0-2;

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**OR**

**VII.** Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 2A):
- A. Used as first-line therapy; **AND**
- B. Given in combination with atezolizumab and carboplatin; **AND**
- C. Confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown;

**OR**

**VIII.** Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 1, 2A):
- A. Used as subsequent therapy after failure of kinase inhibitor targeted agent; **AND**
- B. Given in combination with carboplatin and atezolizumab;

**OR**

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

**OR**

**X.** 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 when used as a single agent (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer); **OR**
- B. Treatment of persistent or recurrent ovarian cancer when used with carboplatin (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**

**XI.** Locally advanced or metastatic adenocarcinoma of the pancreas when the following criteria are met (Label, NCCN 2A):
- A. Used as first-line therapy or later; **AND**
- B. Given in combination with gemcitabine as a single-line of therapy;

**OR**

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

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XIII. 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 for the following:

I. Individual has baseline neutrophil count of less than 1,500 cells/mm$^3$ prior to initiation of Abraxane; OR

II. When the above criteria are not met and for all other indications.

Key References:


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