Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Abraxane (paclitaxel, protein-bound)

Override	Approval Duration
Prior Authorization	1 year

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) pperformance 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):

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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;

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);

OR

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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.

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Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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    d. Hepatobiliary Cancers. V3.2019. Revised August 1, 2019.
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    f. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V3.2019. Revised November 26, 2019.
    g. Pancreatic Adenocarcinoma. V1.2020. Revised November 26, 2019.
    h. Small Bowel Adenocarcinoma. V1.2020. Revised July 30, 2019.
    i. Uterine Neoplasms. V4.2019. Revised September 16, 2019.
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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.