

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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# Abraxane (paclitaxel, protein-bound)

## CG-DRUG-50

Override	Approval Duration
Prior Authorization	1 year

Medication
Abraxane (paclitaxel, protein-bound)

### **APPROVAL CRITERIA**

Requests for Abraxane (paclitaxel, protein-bound) **may be approved** when the following criteria are met:

- I. Breast Cancer
  - A. Individual has relapsed or has metastatic breast cancer and meets the following criteria:
    1. Abraxane is being used as a single agent; **AND**
    2. Abraxane is being used in a single line of therapy.

**OR**

  - B. Individual has any breast cancer and Abraxane is being used as a substitute for solvent-based paclitaxel or docetaxel secondary to documented allergic reaction.
- II. Malignant Melanoma
  - A. Individual has relapsed or has refractory melanoma and meets the following criteria:
    1. Abraxane is being used as a single agent; **AND**
    2. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 following at least one prior therapy.
  - III. Non-Small Cell Lung Cancer (NSCLC)
    - A. Individual has locally advanced or metastatic NSCLC and meets the following criteria:
      1. Abraxane is being used as first-line therapy; **AND**
      2. Abraxane is being given in combination with carboplatin or cisplatin.

**OR**

    - B. Abraxane is being used as a substitute for either solvent-based paclitaxel or docetaxel secondary to documented allergic reaction **or** when conventional premedications (that is, corticosteroids [such as dexamethasone], histamine H1 antagonists, or histamine H2 antagonists) are contraindicated.
  - IV. Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer)
    - A. Individual has persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) and meets the following criteria:
      1. Abraxane is being used as a single agent; **OR**

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.

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2. Arabaxane is being used in combination with carboplatin in a platinum-sensitive individual with confirmed taxane (that is solvent-based paclitaxel or docetaxel) hypersensitivity.

#### V. Pancreatic Cancer

- A. Individual has locally advanced or metastatic adenocarcinoma of the pancreas and meets the following criteria:
  1. Abraxane is being used as first-line therapy or later; **AND**
  2. Abraxane is being given in combination with gemcitabine as a single-line of therapy.

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

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

#### Key References:

Abraxane [Product Information]. Summit, NJ. Abraxis BioScience, LLC., Celgene Corp.; July 2015. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/021660s041lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021660s041lbl.pdf). Accessed on September 17, 2017.

National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on September 17, 2017.

NCCN Clinical Practice Guidelines in Oncology®. © 2016-2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on September 17, 2017.

Bladder Cancer (V5.2017). Revised May 27, 2017.

Breast Cancer (V2.2017). Revised April 6, 2017.

Melanoma (V1.2017). Revised November 10, 2016.

Non-Small Cell Lung Cancer (V8.2017). Revised July 14, 2017.

Ovarian Cancer (including Fallopian Tube Cancer and Primary Peritoneal Cancer) (V3.2017). Revised August 30, 2017.

Pancreatic Adenocarcinoma (V3.2017). Revised September 11, 2017.

Paclitaxel, protein-bound. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated August 29, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on September 17, 2017.

Paclitaxel (Protein Bound) Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised August 10, 2017. Accessed on September 17, 2017.

Taxol Injection [Product Information]. Paramus, NJ. HQ Specialty Pharma; March 3, 2015. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/020262s051lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020262s051lbl.pdf). Accessed on September 17, 2017.

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