

## MEDICAL PRIOR AUTHORIZATION

### Abraxane (paclitaxel, albumin-bound)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. **Metastatic Breast Cancer**  
Abraxane is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
2. **Non-Small Cell Lung Cancer**  
Abraxane is indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
3. **Adenocarcinoma of the Pancreas**  
Abraxane is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

##### B. Compendial Uses

1. Breast cancer
2. NSCLC
3. Pancreatic adenocarcinoma
4. Melanoma
5. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
6. Bladder cancer

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### A. **Pancreatic adenocarcinoma**

Authorization of 12 months may be granted for treatment of pancreatic adenocarcinoma.

##### B. **Breast cancer**

Authorization of 12 months may be granted for treatment of recurrent or metastatic breast cancer.

**C. Non-small cell lung cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of recurrent, locally advanced, or metastatic NSCLC.

**D. Melanoma**

Authorization of 12 months may be granted for treatment of metastatic or unresectable melanoma.

**E. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer**

Authorization of 12 months may be granted for treatment of persistent or recurrent disease.

**F. Bladder cancer**

Authorization of 12 months may be granted for treatment of bladder cancer.

**III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**IV. REFERENCES**

1. Abraxane [package insert]. Summit, NJ: Celgene Corporation; July 2015.
2. The NCCN Drugs & Biologics Compendium<sup>®</sup> © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed February 27, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Breast Cancer (Version 2.2016).© 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 27, 2017.
4. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Non-Small Cell Lung Cancer (Version 4.2017).© 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 27, 2017.
5. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Pancreatic Adenocarcinoma (Version 1.2017).© 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 27, 2017.
6. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Melanoma (Version 1.2017).© 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 9, 2017.
7. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Ovarian Cancer (Version 1.2016).© 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 9, 2017.
8. The NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Bladder Cancer (Version 2.2017).© 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 9, 2017.