

Reference number(s)
1669-A

SPECIALTY GUIDELINE MANAGEMENT

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 metastatic 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. Cutaneous melanoma
5. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
6. Bladder cancer
7. AIDS-related Kaposi sarcoma
8. Endometrial carcinoma
9. Hepatobiliary cancer
10. Uveal melanoma

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.

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C. Non-small cell lung cancer (NSCLC)

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

D. Cutaneous melanoma

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

G. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for treatment of relapsed or refractory advanced AIDS-related Kaposi sarcoma.

H. Endometrial carcinoma

Authorization of 12 months may be granted for treatment of endometrial carcinoma.

I. Hepatobiliary cancer

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

J. Uveal melanoma

Authorization of 12 months may be granted for treatment of uveal melanoma.

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; August 2018.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 25, 2019.
3. The NCCN Clinical Practice Guidelines in Oncology® Breast Cancer (Version 3.2018). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
4. The NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 3.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
5. The NCCN Clinical Practice Guidelines in Oncology® Pancreatic Adenocarcinoma (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
6. The NCCN Clinical Practice Guidelines in Oncology® Cutaneous Melanoma (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
7. The NCCN Clinical Practice Guidelines in Oncology® Ovarian Cancer (Version 2.2018). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
8. The NCCN Clinical Practice Guidelines in Oncology® Bladder Cancer (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.

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9. The NCCN Clinical Practice Guidelines in Oncology® AIDS-Related Kaposi Sarcoma (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
10. The NCCN Clinical Practice Guidelines in Oncology® Uterine Neoplasms (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
11. The NCCN Clinical Practice Guidelines in Oncology® Hepatobiliary Cancers (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.
12. The NCCN Clinical Practice Guidelines in Oncology® Uveal Melanoma (Version 1.2018). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 25, 2019.