Reference number(s)
1669-A

SPECIALTY GUIDELINE MANAGEMENT

Abraxane (paclitaxel, albumin-bound)
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
   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
   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
   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. Non-small cell lung cancer
3. Pancreatic adenocarcinoma
4. Cutaneous melanoma
5. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
6. Kaposi sarcoma
7. Endometrial carcinoma
8. Hepatobiliary cancers: intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer
9. Uveal melanoma
10. Small bowel adenocarcinoma
11. Ampullary adenocarcinoma
12. Cervical cancer

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Pancreatic adenocarcinoma

Authorization of 6 months may be granted for treatment of pancreatic adenocarcinoma.

B. Breast cancer

Authorization of 6 months may be granted for treatment of breast cancer in any of the following settings:

1. Recurrent or metastatic disease
2. Following no response to preoperative systemic therapy
3. As a substitute for paclitaxel or docetaxel due to hypersensitivity reactions or contraindication to standard hypersensitivity premedications

C. Non-small cell lung cancer (NSCLC)

Authorization of 6 months may be granted for treatment of NSCLC in any of the following settings:

1. Recurrent, advanced or metastatic disease
2. As a substitute for paclitaxel or docetaxel due to hypersensitivity reactions or contraindication to standard hypersensitivity premedications

D. Cutaneous melanoma

Authorization of 6 months may be granted for subsequent treatment of metastatic or unresectable cutaneous melanoma, as a single-agent or in combination with carboplatin.

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

Authorization of 6 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer in any of the following settings:

1. Persistent or recurrent disease
2. As a substitute for paclitaxel due to a hypersensitivity reaction to paclitaxel

F. Kaposi sarcoma

Authorization of 6 months may be granted for treatment of Kaposi sarcoma.

G. Endometrial carcinoma

Authorization of 6 months may be granted for treatment of endometrial carcinoma, as a single agent.

H. Hepatobiliary Cancers

Authorization of 6 months may be granted for treatment of unresectable or metastatic intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer, in combination with gemcitabine.

I. Uveal melanoma

Authorization of 6 months may be granted for treatment of uveal melanoma, as single-agent therapy for distant metastatic disease.

J. Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of advanced or metastatic small bowel adenocarcinoma, as a single agent or in combination with gemcitabine.

K. Ampullary Adenocarcinoma

Authorization of 6 months may be granted for treatment of ampullary adenocarcinoma, in combination with gemcitabine.

L. Cervical cancer

Authorization of 6 months may be granted for subsequent treatment of persistent, recurrent, or metastatic cervical cancer, as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Abraxane [package insert]. Summit, NJ: Celgene Corporation; August 2020.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 6, 2023.
3. paclitaxel, albumin-bound [package insert]. Paramus, NJ: TWi Pharmaceuticals USA, Inc.; April 2022.