Reference number(s)
4817-A

STANDARD MEDICARE PART B 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 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. 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, including advanced ampullary cancer[2]
11. Cervical cancer
12. Anal cancer
13. Gastric cancer
14. Head and neck cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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. Neoadjuvant, in sequential combination with an anthracycline and cyclophosphamide
4. 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 treatment of metastatic or unresectable cutaneous melanoma, as a single-agent or in combination with carboplatin as second-line or subsequent therapy.

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

Authorization of 6 months may be granted for treatment of persistent or recurrent epithelial ovarian cancer (including carcinosarcoma [malignant mixed Müllerian tumors], clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors [low malignant potential] with invasive implants), fallopian tube cancer, and primary peritoneal cancer.

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.

H. Hepatobiliary cancers

1. Authorization of 6 months may be granted for treatment of unresectable or metastatic intrahepatic cholangiocarcinoma and extrahepatic cholangiocarcinoma in combination with gemcitabine with or without cisplatin.
2. Authorization of 6 months may be granted for treatment of gallbladder cancer in either of the following settings:
    1. Unresectable or metastatic disease in combination with gemcitabine with or without cisplatin

2. Neoadjuvant chemotherapy for advanced or resectable disease with jaundice in combination with cisplatin and gemcitabine

I. Uveal melanoma
Authorization of 6 months may be granted for treatment of uveal melanoma, as a 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, including advanced ampullary cancer, as a single agent or in combination with gemcitabine.

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

L. Anal cancer
Authorization of 6 months may be granted for treatment of recurrent squamous cell carcinoma of the anal canal.

M. Gastric cancer
Authorization of 6 months may be granted for treatment of gastric cancer refractory to first-line fluoropyrimidine-containing chemotherapy.

N. Head and neck cancer
Authorization of 6 months may be granted for treatment of squamous cell carcinoma of the head and neck, including squamous cell carcinoma of the tongue.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Abraxane
B. Abraxane is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen AND
   2. No evidence of 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® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 8, 2021.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 9, 2021.

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