Abraxane® (paclitaxel, albumin-bound) ~~(Abraxane®;~~ paclitaxel, albumin-bound

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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. ~~Hepato~~biliary tract cancers: intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer
9. Uveal melanoma
10. Small bowel adenocarcinoma
11. Ampullary adenocarcinoma
12. Cervical cancer
13. Bladder 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, in combination with gemcitabine.

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 subsequent treatment of endometrial carcinoma, as a single agent.

H. ~~Hepato~~Biliary Tract Cancers
Authorization of 6 months may be granted for treatment of unresectable, resected gross residual (R2), 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, or unresectable 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.

M. Bladder cancer
Authorization of 6 months may be granted for subsequent treatment of platinum-resistant locally advanced or metastatic bladder cancer.

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.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Abraxane (Paclitaxel Protein-Bound Particles)	Ampullary Adenocarcinoma, Cervical Cancer, Hepatobiliary Cancers: Intrahepatic Cholangiocarcinoma, Extrahepatic Cholangiocarcinoma, and Gallbladder Cancer	Route of Administration: Intravenous 125mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Breast Cancer	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 125mg/m² on days 1, 8, and 15 (28-day cycle) 125mg/m² on days 1 and 8 (21-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Cutaneous Melanoma, Uveal Melanoma	Route of Administration: Intravenous 150mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Endometrial Carcinoma	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 125mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Fallopian Tube Cancer	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 100mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Kaposi Sarcoma	Route of Administration: Intravenous 100mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Non-Small Cell Lung Cancer (NSCLC)	Route of Administration: Intravenous 100mg/m² on days 1, 8, and 15 (21-day cycle) 125mg/m² on days 1, 8, and 15 (28-day cycle) 260mg/m² on day 1 (21-day cycle)

Abraxane (Paclitaxel Protein-Bound Particles)	Ovarian Cancer	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 100mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Pancreatic Adenocarcinoma	Route of Administration: Intravenous 125mg/m² on days 1, 8, and 15 (28-day cycle) 125mg/m² on days 1 and 8 (21-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Primary Peritoneal Cancer	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 100mg/m² on days 1, 8, and 15 (28-day cycle)
Abraxane (Paclitaxel Protein-Bound Particles)	Small Bowel Adenocarcinoma	Route of Administration: Intravenous 260mg/m² on day 1 (21-day cycle) 125mg/m² on days 1, 8, and 15 (28-day cycle)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Abraxane [package insert]. Summit, NJ: Celgene Corporation; October 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 17, 2024.
3. paclitaxel, albumin-bound [package insert]. Paramus, NJ: TWi Pharmaceuticals USA, Inc.; April 2022.
4. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 18, 2024.

EFFECTIVE DATE

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