

# JURISDICTION SPECIFIC MEDICARE PART B

## ABRAXANE (paclitaxel, albumin-bound)

### POLICY

#### I. COVERED USES

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

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

- A.    Breast cancer
- B.    Non-small cell lung cancer
- C.    Adenocarcinoma of the pancreas
- D.    Uveal melanoma
- E.    AIDS-related Kaposi sarcoma
- F.    Small bowel adenocarcinoma
- G.    Epithelial ovarian cancer/Fallopian tube cancer/ Primary peritoneal cancer
- H.    Intrahepatic cholangiocarcinoma
- I.    Extrahepatic cholangiocarcinoma
- J.    Cutaneous melanoma
- K.    Endometrial carcinoma
- L.    Anal cancer
- M.    Gastric adenocarcinoma
- N.    Head and neck cancer
- O.    Urothelial carcinoma of the prostate
- P.    Bladder cancer
- Q.    Hormone refractory prostate carcinoma
- R.    Carcinoma of the renal pelvis and ureter
- S.    Rhabdomyosarcoma
- T.    Leiomyosarcoma
- U.    Gallbladder 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. DOCUMENTATION

Abraxane MedB Jurisdiction K (CT, MA, ME, NH, NY, RI, VT) 2021.docx

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The following documentation must be available, upon request, for all submissions:

- A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
- B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

### III. CRITERIA FOR APPROVAL

#### A. Breast Cancer

Authorization of 12 months may be granted for treatment of breast cancer when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### B. Non-Small Cell Lung Cancer

Authorization of 12 months may be granted for treatment of non-small cell lung cancer when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### C. Adenocarcinoma of the Pancreas

Authorization of 12 months may be granted for treatment of adenocarcinoma of the pancreas when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### D. Uveal Melanoma

Authorization of 12 months may be granted for treatment of uveal melanoma when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### E. AIDS-Related Kaposi Sarcoma

Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### F. Small Bowel Adenocarcinoma

Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma when either of the following criteria is met:

- 1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
- 2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### G. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

Authorization of 12 months may be granted for treatment of epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **H. Intrahepatic cholangiocarcinoma**

Authorization of 12 months may be granted for treatment of intrahepatic cholangiocarcinoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **I. Extrahepatic Cholangiocarcinoma**

Authorization of 12 months may be granted for treatment of extrahepatic cholangiocarcinoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **J. Cutaneous melanoma**

Authorization of 12 months may be granted for treatment of cutaneous melanoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **K. Endometrial Carcinoma**

Authorization of 12 months may be granted for treatment of endometrial carcinoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **L. Anal Cancer**

Authorization of 12 months may be granted for treatment of anal cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **M. Gastric Adenocarcinoma**

Authorization of 12 months may be granted for treatment of gastric adenocarcinoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

#### **N. Head and Neck Cancer**

Authorization of 12 months may be granted for treatment of head and neck cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**O. Urothelial Carcinoma of the Prostate**

Authorization of 12 months may be granted for treatment of urothelial carcinoma of the prostate when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**P. Bladder Cancer**

Authorization of 12 months may be granted for treatment of bladder cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**Q. Hormone Refractory Prostate Cancer**

Authorization of 12 months may be granted for treatment of hormone refractory prostate cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**R. Carcinoma of the Renal Pelvis and Ureter**

Authorization of 12 months may be granted for treatment of carcinoma of the renal pelvis and ureter when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**S. Rhabdomyosarcoma**

Authorization of 12 months may be granted for treatment of rhabdomyosarcoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**T. Leiomyosarcoma**

Authorization of 12 months may be granted for treatment of leiomyosarcoma when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**U. Gallbladder cancer**

Authorization of 12 months may be granted for treatment of gallbladder cancer when either of the following criteria is met:

1. The patient's medical record indicates the patient has received prior therapy with an anthracycline.
2. The patient's medical record indicates that treatment with an anthracycline is clinically contraindicated.

**IV. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
2. Billing and Coding: Paclitaxel (A52450) Version R13. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
4. Abraxane [package insert]. Summitt, NJ: Celgene Corporation; December 2019.
5. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 25, 2021.
6. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed January 25, 2021.