

# Jurisdiction Specific Medicare Part B Abraxane

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Abraxane	paclitaxel, albumin-bound
paclitaxel, albumin-bound (all other brands)	paclitaxel, albumin-bound

## Indications

### 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 FDA-labeled indications and recognized compendial (off-label) uses are below<sup>1,2,4-7</sup>

- Breast cancer
- Non-small cell lung cancer
- Adenocarcinoma of the pancreas
- Uveal melanoma
- Kaposi sarcoma
- Small bowel adenocarcinoma
- Epithelial ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer
- Intrahepatic cholangiocarcinoma
- Extrahepatic cholangiocarcinoma
- Cutaneous melanoma
- Endometrial carcinoma
- Anal cancer
- Gastric cancer
- Head and neck cancer

Reference number(s)
3861-A

- Hormone refractory prostate carcinoma
- Carcinoma of the renal pelvis and ureter
- Rhabdomyosarcoma
- Leiomyosarcoma
- Gallbladder cancer
- Ampullary adenocarcinoma
- Cervical cancer
- Vaginal cancer

Compendial Uses – ICD-10 codes supported by the Medicare Administrative Contractor<sup>1,2</sup>.

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>.

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

## Coverage Criteria

### Breast Cancer<sup>2,4-7</sup>

Authorization of 6 months may be granted for treatment of breast cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

### Non-Small Cell Lung Cancer<sup>2,4-7</sup>

Authorization of 6 months may be granted for treatment of non-small cell lung cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

### Adenocarcinoma of the Pancreas<sup>2,4-6</sup>

Authorization of 6 months may be granted for treatment of adenocarcinoma of the pancreas when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

### Uveal Melanoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of uveal melanoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Kaposi Sarcoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of Kaposi sarcoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Small Bowel Adenocarcinoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of small bowel adenocarcinoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer<sup>2,6,7</sup>

Authorization of 6 months may be granted for treatment of epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Intrahepatic cholangiocarcinoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of intrahepatic cholangiocarcinoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Extrahepatic Cholangiocarcinoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of extrahepatic cholangiocarcinoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.

- Treatment with an anthracycline is clinically contraindicated.

## Cutaneous melanoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of cutaneous melanoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Endometrial Carcinoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of endometrial carcinoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Anal Cancer<sup>2,7</sup>

Authorization of 6 months may be granted for treatment of anal cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Gastric cancer<sup>2,7</sup>

Authorization of 6 months may be granted for treatment of gastric cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Head and Neck Cancer<sup>2,7</sup>

Authorization of 6 months may be granted for treatment of head and neck cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Hormone Refractory Prostate Cancer<sup>1</sup>

Authorization of 6 months may be granted for treatment of hormone refractory prostate cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Carcinoma of the Renal Pelvis and Ureter<sup>1</sup>

Authorization of 6 months may be granted for treatment of carcinoma of the renal pelvis and ureter when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Rhabdomyosarcoma<sup>1</sup>

Authorization of 6 months may be granted for treatment of rhabdomyosarcoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Leiomyosarcoma<sup>1</sup>

Authorization of 6 months may be granted for treatment of leiomyosarcoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Gallbladder cancer<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of gallbladder cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Ampullary adenocarcinoma<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of ampullary adenocarcinoma when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Cervical cancer<sup>6</sup>

Authorization of 6 months may be granted for treatment of cervical cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Vaginal cancer<sup>6</sup>

Authorization of 6 months may be granted for treatment of vaginal cancer when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## All Other Indications<sup>1,2</sup>

Authorization of 6 months may be granted for treatment of all other approvable indications listed in LCA A52450 for albumin-bound paclitaxel when either of the following criteria is met:

- The member's medical record indicates the member has received prior therapy with an anthracycline.
- Treatment with an anthracycline is clinically contraindicated.

## Dosage and Administration

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

## References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 28, 2025.
2. Billing and Coding: Paclitaxel (A52450) Version R25. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 28, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 28, 2025.
4. Abraxane [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.
5. paclitaxel, albumin-bound [package insert]. Weston, FL: Apotex Corp; April 2022.
6. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 28, 2025.
7. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed January 28, 2025.