| Reference number(s) |
| --- |
| 1669-A |

# Medical Prior Authorization
# 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

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.

### FDA-approved Indications[1,3]

#### 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.

#### 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.

#### Adenocarcinoma of the Pancreas

Indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

## Compendial Uses[2,4]

- Breast cancer
- Non-small cell lung cancer
- Pancreatic adenocarcinoma
- Cutaneous melanoma
- Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
- Kaposi sarcoma
- Endometrial carcinoma
- Biliary tract cancers: intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer
- Uveal melanoma
- Small bowel adenocarcinoma
- Ampullary adenocarcinoma
- Cervical cancer
- Vaginal cancer
- Bladder cancer

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

# Coverage Criteria

## Pancreatic adenocarcinoma[1-3]

Authorization of 6 months may be granted for treatment of pancreatic adenocarcinoma, in combination with gemcitabine with or without cisplatin.

## Breast cancer[1-3]

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

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

## Non-small cell lung cancer (NSCLC)[1-3]

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

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

## Cutaneous melanoma[2]

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.

## Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer[2]

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:

- Persistent or recurrent disease
- As a substitute for paclitaxel due to a hypersensitivity reaction to paclitaxel

## Kaposi sarcoma[2]

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

## Endometrial carcinoma[2]

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

## Biliary tract cancers[2]

Authorization of 6 months may be granted for treatment of either of the following in combination with gemcitabine:

- Unresectable, resected gross residual (R2), or metastatic intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer
- Neoadjuvant therapy for resectable locoregionally advanced gallbladder cancer that does not present as jaundice

## Uveal melanoma[2]

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

## Small bowel adenocarcinoma[2]

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.

### Ampullary adenocarcinoma[2]

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

### Cervical cancer[2]

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

### Vaginal cancer[2]

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

### Bladder cancer[4]

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

## Continuation of Therapy

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

## References

1. Abraxane [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 28, 2025.
3. paclitaxel, albumin-bound [package insert]. Weston, FL: Apotex Corp; 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 28, 2025.