Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: PA.CP.PHAR.176
Effective Date: 01/2018
Last Review Date: 04/2026

Description
Protein-bound paclitaxel (Abraxane®) is microtubule inhibitor.

FDA approved indication
Abraxane is indicated for the treatment of:

- Metastatic 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.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of PA Health & Wellness® that Abraxane and paclitaxel, protein bound are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of breast cancer;
2. One of the following (a or b):
   a. Disease is recurrent, metastatic, or unresponsive to preoperative systemic therapy;
   b. History of taxane (e.g., paclitaxel, docetaxel) hypersensitivity;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 260 mg/m^2 every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of NSCLC;
2. One of the following (a or b):
   a. Disease is recurrent, advanced, or metastatic;
   b. History of taxane (e.g., paclitaxel, docetaxel) hypersensitivity;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member must use paclitaxel, unless contraindicated or clinically significant adverse effects are experienced;
6. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 100 mg/m^2 IV on Days 1, 8, and 15 of each 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. Adenocarcinoma of the Pancreas (must meet all)**:**
1. Diagnosis of adenocarcinoma of the pancreas;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Abraxane will be used in combination with gemcitabine*;
   **Gemcitabine may require prior authorization*
5. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 125 mg/m^2 on Days 1, 8 and 15 of each 28-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

D. Additional NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the indications supported by NCCN categories 1, 2A or 2B(a - j):
   a. Kaposi sarcoma, prescribed as subsequent systemic therapy and member is paclitaxel intolerant;
   b. Ampullary adenocarcinoma, prescribed in combination with gemcitabine;
   c. Cervical cancer, prescribed as a single agent as second-line or subsequent therapy;
   d. Recurrent endometrial carcinoma, prescribed as a single agent as second-line or subsequent therapy;
   e. Cholangiocarcinoma or gallbladder cancer, and one of the following (i or ii):
      i. Both of the following (1 and 2):
         1. Disease is unresectable or resected gross residual (R2) disease or metastatic;
         2. Abraxane is prescribed in combination with gemcitabine;

ii. For gallbladder cancer, prescribed as neoadjuvant therapy in combination with gemcitabine;

f. Metastatic or unresectable melanoma (i or ii):
   i. Cutaneous melanoma, prescribed as second-line or subsequent therapy;
   ii. Uveal melanoma, prescribed as a single agent;

g. Ovarian cancer (i or ii)
   i. Disease is persistent or recurrent;
   ii. History of taxane (e.g., paclitaxel, docetaxel) hypersensitivity;

h. Advanced or metastatic small bowel adenocarcinoma;

i. Vaginal cancer, prescribed as a single agent as second-line or subsequent therapy;

j. Other NCCN category 1, 2A, or 2B recommendations;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

E. Other diagnoses/indications *(including NCCN category 1, 2A and 2B indications not already listed).*

1. Refer to PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, meets one of the following (a or b):
   a. New dose does not exceed one of the following (i, ii, or iii):
      i. For breast cancer: 260 mg/m^2 IV every 3 weeks;
      ii. For NSCLC: 100 mg/m^2 IV on Days 1, 8, and 15 of each 21-day cycle;
      iii. For adenocarcinoma of the pancreas: 125 mg/m^2 on Days 1, 8 and 15 of each 28-day cycle
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
NSCLC: non-small cell lung cancer
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
paclitaxel (Taxol®)	For NSCLC: Various combinations	250 mg/m^2 every 3 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): neutrophil counts of < 1,500 cells/mm^3, severe hypersensitivity
- Boxed warning(s): neutropenia

Appendix D: General Information

- Residual Tumor (R) Classification:

R0	no residual tumor	resected, negative margin
R1	microscopic residual tumor	resected, positive margin
R2	macroscopic residual tumor	resected, gross residual disease

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Metastatic breast cancer	260 mg/m^2 IV every 3 weeks	260 mg/m^2
Non-small cell lung cancer	100 mg/m^2 IV on days 1, 8, and 15 of each 21-day cycle	260 mg/m^2
Metastatic adenocarcinoma of the pancreas	125 mg/m^2 IV on days 1, 8 and 15 of each 28-day cycle	260 mg/m^2

V. Product Availability

Injectable suspension: lyophilized powder containing 100 mg of paclitaxel formulated as albumin-bound particles in single-use vial for reconstitution.

VI. References

1. Abraxane Prescribing Information. Summit, NJ: Celgene Corporation; October 2022. Available at http://www.abraxane.com/. Accessed January 30, 2026.
2. Paclitaxel, albumin bound. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 30, 2026.
3. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier.; Updated periodically. Accessed January 30, 2026.
4. National Comprehensive Cancer Network. Breast Cancer Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 30, 2026.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf Accessed January 30, 2026.
6. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 30, 2026.
7. Hermanek P and Wittekind C. Residual tumor (R) classification and prognosis. Semin Surg Oncol. 1994 Jan-Feb;10(1):12-20.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9264	Injection, paclitaxel protein-bound particles, 1 mg

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-10-CM Code	Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0-C24.9	Malignant neoplasm of other and unspecified parts of biliary tract
C25.0-C25.9	Malignant neoplasm of pancreas

ICD-10-CM Code	Description
C34.00-C34.02	Malignant neoplasm of main bronchus
C34.10-C34.12	Malignant neoplasm of upper lobe, bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30-C34.32	Malignant neoplasm of lower lobe, bronchus or lung
C34.80-C34.82	Malignant neoplasm of overlapping sites of bronchus or lung
C34.90-C34.92	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C43.0-C43.8	Melanoma and other malignant neoplasms of skin
C43.9	Malignant melanoma of skin, unspecified
C46.0-C46.9	Kaposi's sarcoma
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011-C50.012	Malignant neoplasm of nipple and areola, female breast
C50.021-C50.022	Malignant neoplasm of nipple and areola, male breast
C50.111-C50.112	Malignant neoplasm of central portion of female breast
C50.121-C50.122	Malignant neoplasm of central portion of male breast
C50.211-C50.212	Malignant neoplasm of upper-inner quadrant of female breast
C50.221-C50.222	Malignant neoplasm of upper-inner quadrant of male breast
C50.311-C50.312	Malignant neoplasm of lower-inner quadrant of female breast
C50.321-C50.322	Malignant neoplasm of lower-inner quadrant of male breast
C50.411-C50.412	Malignant neoplasm of upper-outer quadrant of female breast
C50.421-C50.422	Malignant neoplasm of upper-outer quadrant of male breast
C50.511-C50.512	Malignant neoplasm of lower-outer quadrant of female breast
C50.521-C50.522	Malignant neoplasm of lower-outer quadrant of male breast
C50.611-C50.612	Malignant neoplasm of axillary tail of female breast
C50.621-C50.622	Malignant neoplasm of axillary tail of male breast
C50.811-C50.812	Malignant neoplasm of overlapping sites of female breast
C50.821-C50.822	Malignant neoplasm of overlapping sites of male breast
C50.911-C50.912	Malignant neoplasm of breast of unspecified site, female
C50.921-C50.922	Malignant neoplasm of breast of unspecified site, male
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.1	Malignant neoplasm of endometrium
C56.1-C56.3	Malignant neoplasm of ovary
C57.01-C57.02	Malignant neoplasm of fallopian tube
C57.11-C57.12	Malignant neoplasm of broad ligament
C57.21-C57.22	Malignant neoplasm of round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs

ICD-10-CM Code	Description
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C69.31-C69.32	Malignant neoplasm of choroid
C69.41-C69.42	Malignant neoplasm of ciliary body

Reviews, Revisions, and Approvals	Date
2Q 2018 annual review: added age; NCCN category 2B indication for cervical cancer removed; for all indications: removed requirements to check for contraindications per safety guidance, summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02/2018
2Q 2019 annual review: added NCCN 2A off-label uses: endometrial carcinoma and hepatic cholangiocarcinoma; references reviewed and updated.	04/2019
2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated.	04/2020
Added ICD-10-CM codes C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, and C50.9	06/2020
2Q 2021 annual review: clarified NSCLC to be recurrent, advanced or metastatic per NCCN and revised requirement of medical justification for inability to use paclitaxel to "must use" language; clarified hepatic cholangiocarcinoma as "cholangiocarcinoma," unresectable or metastatic and Abraxane prescribed in combination with gemcitabine per NCCN; references reviewed and updated.	04/2021
2Q 2022 annual review: removed criterion for Abraxane+Tecentriq combination therapy in triple-negative breast cancer as this indication was withdrawn in August 2021 and no longer supported by NCCN; per NCCN, added "unresponsive to preoperative systemic therapy" as a breast cancer status, added gallbladder cancer indication, added single-agent therapy criterion for cutaneous melanoma, uveal melanoma, and endometrial carcinoma indications, removed bladder cancer indication as this is no longer supported; references reviewed and updated.	04/2022
2Q 2023 annual review: removed criterion for prior anthracycline therapy for non-triple negative breast cancer per NCCN; added ampullary adenocarcinoma and cervical cancer as additional NCCN supported indications (off-label); removed HCPCS/CPT code 96413 and 96415; references reviewed and updated.	04/2023
2Q 2024 annual review: clarified language from "Abraxane" to "paclitaxel, protein-bound" where applicable to reduce confusion that policy also applies to generic paclitaxel; for adenocarcinoma of the pancreas, removed criteria that disease is metastatic, unresectable or borderline resectable per NCCN; separated cutaneous melanoma from uveal melanoma as it can be used as a single agent or in combination per NCCN; for cervical cancer, added prescribed as a single agent per NCCN; for gallbladder cancer or	04/2024

Reviews, Revisions, and Approvals	Date
cholangiocarcinoma, added option for treatment with resected gross residual (R2) disease per NCCN; residual tumor classification added to Appendix D; removed no longer valid therapeutic alternatives [anthracyclines, gemcitabine] from Appendix B; added HCPCS code [J9259] and [J9258]; references reviewed and updated.	
2Q 2025 annual review: for ovarian cancer, breast cancer and NSCLC, added option for Abraxane usage for members with history of taxane hypersensitivity per NCCN; for gallbladder cancer, added option to be prescribed as neoadjuvant therapy in combination with gemcitabine per NCCN; for ampullary adenocarcinoma, clarified prescribed in combination with gemcitabine per NCCN; added vaginal cancer, prescribed as a single agent to additional NCCN recommended uses (off-label) section per NCCN; references reviewed and updated. Added the following ICD-10 codes in the ICD-10 Code Table: C50.911-C50.912, C50.921-C50.922, C53.0, C53.1, C53.8, and C53.9. Removed HCPCS code [J9258, J9259]	04/2025
2Q 2026 annual review: clarified off-label NCCN supported indications for Kaposi sarcoma, cervical cancer, endometrial carcinoma, cutaneous melanoma, and vaginal cancer, that Abraxane is prescribed as second-line or subsequent therapy per NCCN; for Kaposi sarcoma, added member is paclitaxel intolerant per NCCN; clarified endometrial carcinoma as recurrent disease and melanoma as metastatic or unresectable disease per NCCN; for all indications extended initial approval duration from 6 to 12 months; added ICD-10 code: C43.9 (correction made to be consistent with revision log entry in 11/11/22); references reviewed and updated.	04/2026