Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: CP.PHAR.176
Effective Date: 07.01.15
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Abraxane and paclitaxel, protein bound is **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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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;*

   * *For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

D. Additional NCCN Recommended Uses (off-label) (must meet all)**:**
1. Prescribed for one of the following NCCN categories 1 and 2A supported indications (a - i):
   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;
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*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Abraxane for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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 for all relevant lines of business 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): severe myelosuppression

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Metastatic breast cancer	260 mg/m^2 IV every 3 weeks	260 mg/m^2
NSCLC	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

VI. Product Availability

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

VII. 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.

The following is a list of procedures codes for which coverage may be provided when billed with a diagnosis code(s) that supports coverage criteria (see list of ICD codes supporting coverage criteria further below).

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

ICD-10-CM Code	Description
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
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
C50.021-C50.022	Malignant neoplasm of nipple and areola, male
C50.111-C50.112	Malignant neoplasm of central portion of breast, female
C50.121-C50.122	Malignant neoplasm of central portion of breast, male
C50.211-C50.212	Malignant neoplasm of upper-inner quadrant of breast, female
C50.221-C50.222	Malignant neoplasm of upper-inner quadrant of breast, male
C50.311-C50.312	Malignant neoplasm of lower-inner quadrant of breast, female
C50.321-C50.322	Malignant neoplasm of lower-inner quadrant of breast, male
C50.411-C50.412	Malignant neoplasm of upper-outer quadrant of breast, female
C50.421-C50.422	Malignant neoplasm of upper-outer quadrant of breast, male
C50.511-C50.512	Malignant neoplasm of lower-outer quadrant of breast, female
C50.521-C50.522	Malignant neoplasm of lower-outer quadrant of breast, male
C50.611-C50.612	Malignant neoplasm of axillary tail of breast, female
C50.621-C50.622	Malignant neoplasm of axillary tail of breast, male
C50.811-C50.812	Malignant neoplasm of overlapping sites of breast, female
C50.821-C50.822	Malignant neoplasm of overlapping sites of breast, male
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

ICD-10-CM Code	Description
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
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	P & T Approval Date
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; added requirement for use of generic Abraxane. Removed codes C67.0-C67.9 and Z85.51. references reviewed and updated.	04.18.22	05.22
Template changes applied to other diagnoses/indications.	10.03.22	
Added to 04.18.22 revision log entry that codes C67.0-C67.9 and Z85.51 were removed. Removed codes corresponding to previously removed bladder cancer indication: C65.1, C65.2, C68.0, and Z85.53. Added code C43.9. Added codes for gallbladder cancer, including of the biliary duct: C23, C24.0, C24.1, C24.8 and C24.9. Added code C56.3 to include malignant neoplasm of bilateral ovaries. Removed codes for personal history of malignant neoplasms: Z85.05, Z85.068, Z85.07, Z85.118, Z85.3, Z85.42, Z85.43, Z85.44, Z85.820, Z85.840.	11.11.22	
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.	01.28.23	05.23
Added HCPCS code [J9259]	05.24.23	
Added HCPCS code [J9258]	10.26.23	
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	01.26.24	05.24

Reviews, Revisions, and Approvals	Date	P & T Approval Date
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 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; references reviewed and updated.		
Removed HCPCS code [J9258]	08.07.24	
Removed HCPCS code [J9259].	11.06.24	
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: C53.0, C53.1, C53.8, and C53.9.	02.18.25	05.25
Added step therapy bypass for IL HIM per IL HB 5395.	07.09.25	
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, removed requirement of HIV related and 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 for Medicaid and HIM, 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. Added ICHRA line of business.	03.30.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.