Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: CP.PHAR.176
Effective Date: 07.01.15
Last Review Date: 05.21
Line of Business: Commercial, HIM, 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 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. Disease is recurrent or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. For triple negative breast cancer (i.e., estrogen, progesterone, and human epidermal growth factor receptor 2 [HER2] negative): Prescribed in combination with Tecentriq®;*
      **Prior authorization is required for Tecentriq*
   b. For non-triple negative breast cancer: Prior therapy* included an anthracycline (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin), unless all are contraindicated;
      **Prior authorization may be required for prior therapies*

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: 6 months

B. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member must use paclitaxel, unless contraindicated or clinically significant adverse effects are experienced;
5. 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: 6 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. Disease is metastatic, unresectable, or borderline resectable;
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: 6 months

D. Additional NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the indications supported by NCCN categories 1 and 2A (a - g):
   a. AIDS-related Kaposi sarcoma;
   b. Bladder cancer;
   c. Cutaneous or uveal melanoma;
   d. Endometrial carcinoma;
   e. Cholangiocarcinoma and member meets both of the following (i and ii):
      i. Disease is unresectable or metastatic;
      ii. Abraxane is prescribed in combination with gemcitabine;
   f. Relapsed ovarian cancer;
   g. Advanced or metastatic small bowel adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. 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: 6 months

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace 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. 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: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace 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 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
anthracyclines (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin)	For breast cancer: Refer to prescribing information	Refer to prescribing information
paclitaxel (Taxol®)	For NSCLC: Various combinations	250 mg/m^2 every 3 weeks
gemcitabine (Gemzar®)	For adenocarcinoma of the pancreas: 1,000 mg/m^2 IV over 30 to 40 minutes on days 1, 8, and 15 preceded by nab-paclitaxel (125 mg/m^2 IV over 30 to 40 minutes on days 1, 8, and 15) every 28 days	1000 mg/m^2 once weekly for up to 7 consecutive weeks
Tecentriq® (atezolizumab)	For breast cancer: 840 mg IV on days 1 and 15	840 mg/2 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

V. 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

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; August 2020. Available at http://www.abraxane.com/. Accessed February 19, 2021.
2. Paclitaxel, albumin bound. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 19, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included 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).

CPT® /HCPCS Codes	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration; each additional hour (List separately in addition to code for primary procedure)
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
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

ICD-10-CM Code	Description
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
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
C50.9	Malignant neoplasm of breast of unspecified site
C54.1	Malignant neoplasm of endometrium
C56.1-C56.2	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
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C65.1 – C65.2	Malignant neoplasm of renal pelvis
C67.0 – C67.9	Malignant neoplasm of bladder
C68.0	Malignant neoplasm of urethra
Z85.05	Personal history of malignant neoplasm of liver
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs
Z85.51	Personal history of malignant neoplasm of bladder

ICD-10-CM Code	Description
Z85.53	Personal history of renal pelvis
Z85.820	Personal history of malignant melanoma of skin

Reviews, Revisions, and Approvals	Date	P & T Approval Date
Removed the following: severe hypersensitivity reaction to Abraxane; member has been advised to use birth control. Added that peripheral blood cell count level will be monitored for bone marrow suppression. Added additional NCCN recommended uses for breast cancer and NSCLC. Approval duration changed to 3 and 6 months for initial and renewal request to 6 and 12 months respectively.	07.17	07.17
2Q 2018 annual review: converted to new template; added HIM; 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.	02.07.18	05.18
Removed codes C53.0-C53.9 and Z85.41 per 02.07.18 criteria change above. Added codes for Kaposi Sarcoma C46.0-C46.9	02.05.19	
2Q 2019 annual review: added NCCN 2A off-label uses: endometrial carcinoma and hepatic cholangiocarcinoma; references reviewed and updated.	02.05.19	05.19
Added the following ICD-10-CM codes as medically necessary: C22.1, C54.1, Z85.05, Z85.42. Deleted the following prostate cancer codes from the medically necessary list as it is not a medically necessary indication: C61, Z85.46.	04.23.19	
2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated. Added ICD-10-CM codes C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, and C50.9 as supporting medical necessity.	02.16.20	05.20
Added Commercial line of business to allow for Payment Integrity to process claims.	08.06.20	
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 for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	02.19.21	05.21

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.

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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.