Clinical Policy: Paclitaxel, protein-bound (Abraxane)

Reference Number: PA.CP.PHAR.176
Effective Date: 01/18
Last Review Date: 04/19

Revision Log
Coding Implications

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 Pennsylvania Health and Wellness® 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. Prior therapy included an anthracycline (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin) unless contraindicated;
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: 6 months

B. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of non-small cell lung cancer (NSCLC);
2. Medical justification supports inability to use paclitaxel;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;

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*).

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;
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*).

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, b, c, d, e, or f):
   a. AIDS-related Kaposi sarcoma;
   b. Bladder cancer;
   c. Cutaneous or uveal melanoma;
   d. Endometrial carcinoma;
   e. Hepatic cholangiocarcinoma;
   f. Relapsed ovarian cancer;
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*).

Approval duration: 6 months

E. Other diagnoses/indications *(including NCCN category I and 2A 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, meets one of the following (a or b):
   a. 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. 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.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
FDA: Food and Drug Administration
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: 135 mg/m^2 IV administered over 24 hours followed by cisplatin (75 mg/m^2 IV) every 3 weeks based on clinical status of the patient	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

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.

IV. Dosage and Administration

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

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; July 2015. Available at http://www.abraxane.com/. Accessed February 7, 2018.
2. NCCN Guidelines® & Clinical Resources. Paclitaxel, albumin bound. NCCN Drugs & Biologics Compendium. National Comprehensive Cancer Network, Inc. Accessed February 7, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 7, 2018.

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 2017, 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® /HPCS 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
C25.0-C25.9	Malignant neoplasm of pancreas
C33	Malignant neoplasm of trachea
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
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
C53.0 – C53.9	Malignant neoplasm of cervix uteri
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
C61	Malignant neoplasm of prostate
C65.1 – C65.2	Malignant neoplasm of renal pelvis
C66.1- C66.2	Malignant neoplasm of ureter
C67.0 – C67.9	Malignant neoplasm of bladder

ICD-10-CM Code	Description
C68.0	Malignant neoplasm of urethra
D09.0	Carcinoma in situ of bladder
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
Z85.41	Personal history of malignant neoplasm of cervix uteri
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs
Z85.46	Personal history of malignant neoplasm of prostate
Z85.51	Personal history of malignant neoplasm of bladder
Z85.53	Personal history of malignant neoplasm of renal pelvis
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z85.820	Personal history of malignant melanoma of skin

Reviews, Revisions, and Approvals	Date	Approval 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.	02.07.18	
2Q 2019 annual review: added NCCN 2A off-label uses: endometrial carcinoma and hepatic cholangiocarcinoma; references reviewed and updated.	04/19	