Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: LA.PHAR.176
Effective Date: 06.17.22
Last Review Date: 06.23.25~~10.03.24~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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 Louisiana Healthcare Connection 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):
   ~~2.~~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;

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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. One of the following (a or b):
   a. Disease is recurrent, advanced, or metastatic;
   b. History of taxane (e.g., paclitaxel, docetaxel) hypersensitivity;

~~2.~~3. Prescribed by or in consultation with an oncologist;

~~3.~~4. Age ≥ 18 years;

~~4.~~5. Member must use paclitaxel, unless contraindicated or clinically significant adverse effects are experienced;

~~5.~~6. For Abraxane requests, member must use paclitaxel protein-bound particles, if available, unless contraindicated or clinically significant adverse effects are experienced;

~~6.~~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: 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. 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: 6 months

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 - ~~h~~i):
   a. AIDS-related Kaposi sarcoma;
   b. Ampullary adenocarcinoma, prescribed in combination with gemcitabine;
   c. Cervical cancer, prescribed as a single agent;
   d. Endometrial carcinoma, prescribed as a single agent;

e. Cholangiocarcinoma or gallbladder cancer, and ~~member meets both~~one of the following (i ~~and~~or ii):
   i. Both of the following (1 and 2);
      ~~i.~~1) Disease is unresectable or resected gross residual (R2) disease, or metastatic;
      ~~ii.~~2) Abraxane is prescribed in combination with gemcitabine;
   ii. For gallbladder cancer, prescribed as neoadjuvant therapy in combination with gemcitabine;
f. Melanoma (i or ii):
   i. Cutaneous melanoma;
   ii. Uveal melanoma, prescribed as a single agent;
g. ~~Relapsed ovarian~~Ovarian cancer (i or ii);
   i. Disease is persistent or recurrent;
   ~~g.~~ii. History of taxane (e.g., paclitaxel, docetaxel) hypersensitivity;
h. Advanced or metastatic small bowel adenocarcinoma;
i. Vaginal cancer, prescribed as a single agent;

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: 6 months

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 LA.PMN.255
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 LA.PMN.53

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II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connection 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: 12 months

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 LA.PMN.255
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 LA.PMN.53

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 policy LA.PMN.53

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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 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
~~Non-small cell lung cancer~~ 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 ~~18, 2024~~13, 2025.

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2. Paclitaxel, albumin bound. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed ~~February 5, 2024~~January 27, 2025.
3. Clinical Pharmacology [database online]. ~~Tampa, FL: Gold Standard, Inc.~~Philadelphia, PA: Elsevier.. Updated periodically. Accessed ~~February 5, 2024~~January 27, 2025.
4. National Comprehensive Cancer Network. Breast Cancer Version ~~1~~6.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed ~~February 5, 2024~~January 27, 2025.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.~~2024~~2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf Accessed ~~February 5, 2024~~January 27, 2025.
6. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version ~~1.2024~~3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed ~~February 5, 2024~~January 27, 2025.
7. Hermanek P and Wittekind C. Residual tumor (R) classification and prognosis. Semin Surg Oncol. 1994 Jan-Feb;10(1):12-20

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 2021, 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.

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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
J9264	Injection, paclitaxel protein-bound particles, 1 mg
~~J9259~~	~~Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to J9264, 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).

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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

ICD-10-CM Code	Description
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
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
C57.11-C57.12	Malignant neoplasm of broad ligament
C57.21-C57.22	Malignant neoplasm of round ligament

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ICD-10-CM Code	Description
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

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	04.22	06.17.22
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. 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. Template changes applied to other diagnoses/indications. Added blurb this policy is for medical benefit only.	06.27.23	10.05.23
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 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. Added HCPCS code [J9258]	05.26.24	08.20.24
Removed HCPCS code [J9258]	10.03.24	01.27.25
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	06.23.25	

Reviews, Revisions, and Approvals	Date	LDH Approval Date
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; Removed HCPCS code [J9259].		

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

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