# Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: ERX.SPA.230
Effective Date: 06.01.18
Last Review Date: 05.20
Last Line of Business: Commercial, Medicaid

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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent or metastatic;
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® (atezolizumab);*
      **Tecentriq requires prior authorization*
   b. For non-triple negative breast cancer: Prior therapy* included an anthracycline (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin), unless all are contraindicated;
      **Prior therapies may require prior authorization*
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 NSCLC;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Medical justification supports inability to use paclitaxel;
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. Hepatic cholangiocarcinoma;
   f. 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. All Indications in Section I** (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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, request 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## 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 – ERX.PA.01 or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
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 |
|---|---|---|
| anthracyclines (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin) | For breast cancer:<br>Refer to prescribing information | Refer to prescribing information |
| paclitaxel (Taxol®) | For NSCLC:<br>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:<br>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 | 1,000 mg/m$^2$ once weekly for up to 7 consecutive weeks |
| Tecentriq® (atezolizumab) | For breast cancer:<br>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$^3$, 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$^2$ IV |
| NSCLC | 100 mg/m$^2$ IV on days 1, 8, and 15 of each 21-day cycle | 260 mg/m$^2$ IV |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| 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 |

**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; December 2019. Available at http://www.abraxane.com/. Accessed February 16, 2020.
2. Paclitaxel, albumin bound. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 16, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 16, 2020.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created. | 02.27.18 | 05.18 |
| 2Q 2019 annual review: added NCCN 2A off-label uses: endometrial carcinoma and hepatic cholangiocarcinoma; references reviewed and updated. | 02.05.19 | 05.19 |
| 2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated. | 02.16.20 | 05.20 |

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.