Paclitaxel protein-bound (Abraxane®) **Paclitaxel protein-bound (american regent)** **Paclitaxel protein-bound (teva)**	**Place of Service** **Office Administration** **Outpatient Facility Infusion Administration** **Infusion Center Administration** **HCPCS** • Abraxane: **J9264** per 1 mg • Paclitaxel protein-bound (american regent): **J9259** per 1 mg • Paclitaxel protein-bound (teva): **J9258** per 1 mg

Conditions listed in policy (*see criteria for details*)

- Ampullary adenocarcinoma
- AIDS-related Kaposi sarcoma
- Breast cancer
- Biliary tract cancer
- Cervical cancer
- Endometrial carcinoma
- Epithelial ovarian cancer
- Fallopian tube cancer
- Melanoma: cutaneous
- Melanoma: uveal
- Non-small cell lung cancer
- Pancreatic cancer
- Primary peritoneal cancer
- Small bowel adenocarcinoma

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Microtubule inhibitor, paclitaxel nanoparticles bound to albumin. Albumin has been shown to accumulate in growing tumors, which may contribute to the efficacy of paclitaxel.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Abraxane® (protein-bound paclitaxel) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Ampullary adenocarcinoma

1. Used in combination with gemcitabine

Covered Doses
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C24.1

AIDS-related Kaposi sarcoma

1. Subsequent treatment

Covered Doses
Up to 100 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Four cycles (12 doses)

ICD-10:
C46.0, C46.1, C46.2, C46.3, C46.4, C46.50, C46.51, C46.52, C46.7, C46.9

Breast cancer

1. Contraindication, intolerance, or failure on paclitaxel or docetaxel, **OR**
2. Meets both of the following:
    a. Either of the following:
        i. Inflammatory breast cancer with no response to preoperative systemic therapy, or
        ii. Recurrent unresectable or metastatic disease

    AND

    b. Meets one of the following:
        i. Being used as a single agent or in combination with carboplatin for HER2-negative disease, or
        ii. Being used as a single agent or in combination with carboplatin for triple-negative disease, or
        iii. Either of the following:
            1. ***Effective through 7/30/2023***: Being used in combination with trastuzumab as third line and beyond for HER2-positive disease, or
            2. ***Effective 7/31/2023 and after***: Being used in combination with trastuzumab as fourth line and beyond for HER2-positive disease

        or

        iv. Being used with Keytruda for triple-negative PD-L1 positive breast cancer

Covered Doses
Up to 125 mg/m^2 IV infusion on days 1 and 8 of each 21-day cycle, OR
Up to 150 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle, OR
Up to 260 mg/m^2 IV infusion on day 1 of each 21-day cycle
Coverage Period
Indefinite

ICD-10:
C50.X11, C50.X12, C50.X19 (X = numbers 0-6, 8, 9),

C50.X21, C50.X22, C50.X29 (X=numbers 1-6, 8, 9), Z85.3

Biliary tract cancer (including cholangiocarcinoma)

1. Unresectable or metastatic disease, **AND**
2. Being used in combination with gemcitabine

Covered Doses
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle, or
Up to 100 mg/m^2 IV infusion on days 1 and 8 of each 21-day cycle

Coverage Period
Indefinite

ICD-10:
C22.1, C24.0, C24.8, C24.9

Cervical cancer

1. Persistent, recurrent, or metastatic disease, **AND**
2. Being used as a single agent for second-line or subsequent therapy, **AND**
3. Intolerance or contraindication to standard paclitaxel

Covered Doses
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C53.0, C53.1, C53.8, C53.9

Endometrial carcinoma

1. Used as a single agent, **AND**
2. Intolerance or contraindication to standard paclitaxel

Covered Doses
Up to 260 mg/m^2 IV infusion on day 1 of each 21-day cycle, or
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C54.0-C54.3, C54.8, C54.9, C55

Epithelial ovarian cancer/ Fallopian tube cancer/ Primary peritoneal cancer

1. Patient has undergone treatment with a platinum-based chemotherapy or other systemic chemotherapy if unable to use a platinum agent, **AND**
2. Being used as a single agent or in combination with carboplatin, **AND**
3. Intolerance, contraindication, or medical rationale why standard paclitaxel cannot be used

Covered Doses
Up to 260 mg/m^2 IV infusion on day 1 of each 21-day cycle, OR
Up to 100 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
One year
Re-authorization: Yearly, based on continued response

ICD-10:
C48.1, C48.2, C48.8, C56.1, C56.2, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9, Z85.43

Melanoma: cutaneous

1. Unresectable or metastatic disease, **AND**
2. Patient has received previous systemic treatment for unresectable or metastatic disease, **AND**
3. Intolerance or contraindication to standard paclitaxel

Covered Doses
Up to 150 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9, C79.31, C80.0, C80.1, Z85.820

Melanoma: uveal

1. Metastatic disease, **AND**
2. Being used as a single agent, **AND**
3. Intolerance or contraindication to standard paclitaxel

Covered Doses
Up to 150 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C69.30-C69.32, C69.40 -C69.42, C69.60-C69.62

Non-small cell lung cancer

1. Recurrent, advanced, or metastatic disease, **AND**
2. Either of the following:
    a. In combination with Tecentriq and carboplatin for nonsquamous histology, or
    b. Intolerance, contraindication, or medical rationale why standard paclitaxel cannot be used and one of the following:
        i. Single agent use, or
        ii. In combination with carboplatin, or
        iii. In combination with Keytruda and either carboplatin or cisplatin for squamous histology, or
        iv. In combination with Imjudo, Imfinzi, and carboplatin

Covered Doses
Up to 100 mg/m^2 IV infusion on days 1, 8, and 15 of each 21-day cycle, or
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle, or
Up to 260 mg/m^2 IV infusion on day 1 of each 21-day cycle

Coverage Period
Indefinite

ICD-10:
C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118

<u>Pancreatic cancer</u>

1. Used in combination with gemcitabine, and with or without cisplatin

Covered Doses
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle

Coverage Period
Indefinite

ICD-10:
C25.0-C25.3, C25.7-C25.9, Z85.07

<u>Small bowel adenocarcinoma</u>

1. Advanced or metastatic disease, **AND**
2. Used as a single agent or in combination with gemcitabine, **AND**
3. Intolerance or contraindication to standard paclitaxel

Covered Doses
Up to 260 mg/m^2 IV infusion on day 1 of each 21-day cycle (single agent use)
Up to 125 mg/m^2 IV infusion on days 1, 8, and 15 of each 28-day cycle (with gemcitabline)

Coverage Period
Indefinite

ICD-10:

C17.0, C17.1, C17.2, C17.3, C17.8, C17.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Abraxane® (protein-bound paclitaxel) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
100 mg (single-use vial)

(6) References

- Abraxane® (paclitaxel protein-bound) [Prescribing Information]. Summit, NJ: Celgene Corporation; 8/2020.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Abraxane® (2023). Available at: www.nccn.org/.
- National Comprehensive Cancer Network. Ampullary Adenocarcinoma. (Version 2.2022). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Biliary Tract Cancers (Version 1.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Kaposi Sarcoma (Version 1.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Melanoma: Cutaneous (Version 2.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Melanoma: Uveal (Version 2.2022). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 2.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer (Version 1.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Pancreatic Adenocarcinoma (Version 2.2022). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Small Bowel Adenocarcinoma (Version 1.2023). Available at: www.nccn.org/
- National Comprehensive Cancer Network. Uterine Neoplasms (Version 1.2023). Available at: www.nccn.org/

(7) Policy Update

Date of last revision: 4Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- Added new HCPCS for paclitaxel protein-bound (teva): J9258 per 1 mg, effective 1/1/2024 and after

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee