UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Paclitaxel Albumin-Bound Products Utilization Management Medical Policy
- Abraxane® (paclitaxel albumin-bound suspension, intravenous infusion – Celgene, generic)

REVIEW DATE: 10/02/2024

OVERVIEW

Paclitaxel albumin-bound, a microtubule inhibitor, is indicated for the following uses:[1]

- **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 contraindicated).
- **Non-small cell lung cancer (NSCLC)**, in combination with carboplatin, for the first-line treatment of locally advanced or metastatic disease in patients who are not candidates for curative surgery or radiation therapy.
- **Pancreatic adenocarcinoma,** in combination with gemcitabine, for the first-line treatment of patients with metastatic disease.

Limited dosing is available regarding use of paclitaxel albumin-bound for conditions listed under "Other Uses with Supportive Evidence". Recommended doses in the product label for approved uses include 100 mg/m^2 administered by intravenous (IV) infusion three times in each 21-day cycle, 125 mg/m^2 administered by IV infusion three times in each 28-day cycle, and 260 mg/m^2 administered by IV infusion once every 21 days.[1]

Guidelines

Paclitaxel albumin-bound is addressed in a variety of National Comprehensive Cancer Network (NCCN) guidelines:

- **Breast cancer:** Guidelines (version 4.2024 – July 3, 2024) recommend paclitaxel albumin-bound in combination with Keytruda® (pembrolizumab intravenous infusion) as one of the preferred regimens for programmed death-ligand 1 (PD-L1) positive triple-negative breast cancer (initial therapy – category 1, subsequent therapy – category 2A).[2,3] Paclitaxel albumin-bound, as a single agent or in combination with carboplatin, is recommended for recurrent, unresectable (local or regional) or metastatic HER2-negative disease; and in combination with trastuzumab for recurrent, unresectable (local or regional) or metastatic HER2-positive disease. It is noted that paclitaxel albumin-bound may be substituted for paclitaxel or docetaxel due to medical necessity (i.e., hypersensitivity reaction).
- **NSCLC:** Guidelines (version 10.2024 – September 23, 2024) recommend paclitaxel albumin-bound as first-line therapy for recurrent, advanced, or metastatic PD-L1 expression positive (≥ 1%) tumors that are negative for *EGFR*, *ALK*, *ROS1*, *BRAF*, *NTRK1/2/3*, *MET*, and *RET*, in combination with Keytruda and carboplatin for squamous cell histology, and in combination with carboplatin and Tecentriq® (atezolizumab intravenous infusion) for non-squamous cell histology.[3,4] Paclitaxel albumin-bound is recommended for the treatment of recurrent, advanced, or metastatic squamous cell or nonsquamous cell disease, as a single-agent or in combination with carboplatin with or without Keytruda or Tecentriq, in a variety of clinical situations.
- **Pancreatic adenocarcinoma:** Guidelines (version 3.2024 – August 2, 2024) recommend therapy with paclitaxel albumin-bound in a variety of settings.[3,5] This includes neoadjuvant therapy; first-

line or induction therapy followed by chemoradiation; first-line for metastatic disease (category 1); and in second-line settings after recurrence.

- **Other Uses with Supportive Evidence:** The NCCN Compendium supports the use of paclitaxel albumin-bound for the following conditions: Kaposi sarcoma, intra or extrahepatic cholangiocarcinoma, cervical cancer, ampullary adenocarcinoma, gallbladder cancer, endometrial carcinoma, melanoma, ovarian/fallopian/primary peritoneal cancer, small bowl adenocarcinoma, vaginal cancer, and uveal melanoma.[6-15] The criteria are consistent with the guideline recommendations.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of paclitaxel albumin-bound. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with paclitaxel albumin-bound as well as the monitoring required for adverse events and long-term efficacy, approval requires paclitaxel albumin-bound to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of paclitaxel albumin-bound is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. Breast Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following criteria (i or ii):

i. Patient has recurrent or metastatic breast cancer and meets ONE of the following criteria (a, b, or c):

a) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; OR

b) Patient has programmed death ligand-1 (PD-L1)-positive, triple-negative breast cancer and medication will be used in combination with Keytruda (pembrolizumab intravenous infusion); OR

c) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease and paclitaxel albumin-bound will be used in combination with trastuzumab; OR

ii. Patient meets BOTH of the following criteria (a and b):

a) Patient has had a hypersensitivity reaction to paclitaxel or docetaxel; AND

b) Patient meets ONE of the following criteria [(1) or (2)]:

(1) The medication will be used for human epidermal growth factor receptor 2 (HER2)-negative disease; OR

(2) The medication will be used for HER2-positive disease in combination with trastuzumab; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following (A or B):

A) Approve up to 260 mg/m^2 administered as an intravenous infusion no more frequently than once every 3 weeks.
B) Approve up to 125 mg/m^2 administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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2. Non-Small Cell Lung Cancer (NSCLC). Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC); AND
C) Patient meets ONE of the following criteria (i, ii, iii, iv, or v):
i. Patient meets BOTH of the following (i and ii):
a) The tumor is negative or unknown for targetable mutations; AND
Note: Examples of targetable mutations are epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, ROS proto-oncogene 1 (*ROS1*) and *BRAF*, *NTRK1/2/3*, *MET*, *RET*, and *ERBB2* (HER2). May be *KRAS G12C* mutation positive.
b) Paclitaxel albumin-bound is used as initial or subsequent therapy; OR
ii. Paclitaxel albumin-bound is used as subsequent therapy and the patient meets BOTH of the following (a and b):
a) The tumor is positive for one of the following [(1), (2), (3), or (4)]:
(1) Epidermal growth factor receptor (*EGFR*) exon 19 deletion or exon 21 *L858R* mutation; OR
(2) Epidermal growth factor receptor (*EGFR*) *S768I*, *L861Q*, and/or *G719X* mutation; OR
(3) Anaplastic lymphoma kinase (*ALK*) rearrangement positive; OR
(4) *ROS1* rearrangement positive; AND
b) Patient has received targeted drug therapy for the specific mutation; OR
Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), or Vizimpro (dacomitinib tablets).
iii. Patient meets BOTH of the following (a and b):
a) The tumor is positive for one of the following [(1) or (2)]:
(1) Epidemal growth factor receptor (*EGFR*) exon 20; OR
(2) *ERBB2* (HER2) mutation positive; AND
b) Paclitaxel albumin-bound is used first-line; OR
iv. Patient meets BOTH of the following (a and b):
a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]:
(1) *BRAF V600E* mutation-positive; OR
(2) *MET* exon 14 skipping mutation; OR
(3) *RET* rearrangement; OR
(4) *NTRK*1/2/3 gene-fusion; AND
b) Paclitaxel albumin-bound is used as either first-line or subsequent therapy; OR
v. Patient has experienced a hypersensitivity reaction after receiving paclitaxel or docetaxel and meets ONE of the following criteria (a or b):
a) Patient had hypersensitivity reaction despite receiving premedication; OR
b) Standard hypersensitivity premedications are contraindicated; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 100 mg/m^2 administered as an intravenous infusion no more frequently than three times in each 21-day cycle.

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3. Pancreatic Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** The medication will be used in combination with gemcitabine; AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 125 mg/m^2 as an intravenous infusion no more frequently than three times in each 28-day cycle.

Other Uses with Supportive Evidence

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4. Ampullary Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **D)** Patient is ≥ 18 years of age; AND
- **E)** The medication will be used in combination with gemcitabine; AND
- **F)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 125 mg/m^2 as an intravenous infusion no more frequently than three times in each 28-day cycle.

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5. Biliary Tract Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Patient has gallbladder cancer; AND
    - **b)** The medication is used as neoadjuvant therapy; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** Patient has unresectable, resected gross residual, or metastatic disease; AND
    - **b)** Patient has ONE of the following conditions [(1), (2) or (3)]:
      - **(1)** Gallbladder cancer; OR
      - **(2)** Intrahepatic cholangiocarcinoma; OR
      - **(3)** Extrahepatic cholangiocarcinoma; AND
- **C)** The medication is used in combination with gemcitabine; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing: Approve ONE of the following (A or B):
- **A)** Approve up to 125 mg/m^2 administered as an intravenous infusion given no more frequently than twice every 21 days; OR
- **B)** Approve up to 125 mg/m^2 administered as an intravenous infusion given no more frequently than three times every 28 days.

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6. Cervical Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND

B) The medication will be used as subsequent therapy; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 125 mg/m^2 as an intravenous infusion no more frequently than three times in each 28-day cycle.

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7. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent or metastatic disease; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve doses between 100 mg/m^2 and 260 mg/m^2 administered as an intravenous infusion given no more frequently than once every 21 days.

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8. Kaposi Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one systemic chemotherapy; AND
Note: Examples of systemic chemotherapy are doxorubicin and paclitaxel.
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 100 mg administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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9. Melanoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has unresectable or metastatic melanoma; AND
C) At least one other systemic therapy for melanoma has been tried; AND
Note: Examples of systemic therapy are Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Yervoy (ipilimumab intravenous infusion), high dose Proleukin (aldesleukin intravenous infusion); cytotoxic agents (e.g., dacarbazine, temozolomide, paclitaxel, carboplatin), imatinib, Zelboraf (vemurafenib tablets), Tafinlar (dabrafenib capsules), Mekinist (trametinib tablets).
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 150 mg/m^2 administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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10. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient meets BOTH of the following (a and b):
a) Patient has persistent or recurrent disease; AND
b) At least one other systemic chemotherapy regimen has been tried; OR
Note: Examples of chemotherapy are docetaxel, paclitaxel plus carboplatin.

ii. Patient has had a hypersensitivity reaction to paclitaxel or docetaxel; AND

C) The medication is prescribed by or in consultation with an oncologist

Dosing. Approve ONE of the following (A or B):

A) Approve up to 260 mg/m^2 given as an intravenous infusion no more frequently than once every 3 weeks; OR

B) Approve up to 100 mg/m^2 administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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11. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has advanced or metastatic disease; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing: Approve ONE of the following doses (A or B):

A) Approve up to 260 mg/m^2 given as an intravenous infusion no more frequently than once every 3 weeks; OR

B) Approve up to 125 mg/m^2 administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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12. Uveal Melanoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has metastatic or unresectable disease; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing: Approve up to 150 mg/m^2 administered as an intravenous infusion given no more frequently than three times in each 28-day cycle.

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13. Vaginal Cancer. Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) The medication will be used as subsequent therapy; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 125 mg/m^2 as an intravenous infusion no more frequently than three times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Abraxane is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Non-Small Cell Lung Cancer:** Added exon 21 to the criterion Epidermal growth factor receptor (*EGFR*) exon 19 deletion or exon 21 *L858R* mutation.	12/06/2023
Early Annual Revision	**Non-Small Cell Lung Cancer:** Removed *KRAS* and added may be *KRAS G12C* mutation positive to the Note. Removed *KRAS G12C* as an option for first-line use. **Biliary Tract Cancer:** Added patient has gallbladder cancer and medication is used as neoadjuvant therapy as new condition of approval. Added resected gross residual to requirement that the patient has unresectable, resected gross residual, or metastatic disease. Moved patient has unresectable, resected gross residual, or metastatic disease; and has gallbladder cancer, intrahepatic cholangiocarcinoma, or extrahepatic cholangiocarcinoma to an option for approval. **Endometrial Carcinoma:** Removed "high-risk" from requirement that the patient has recurrent or metastatic disease. **Melanoma:** Removed "advanced" from requirement that the patient has unresectable or metastatic disease. **Small Bowel Adenocarcinoma:** Removed requirement that if the disease has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H), the patient has progressed on Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Jemperli (dostarlimab intravenous infusion). **Vaginal Cancer:** Added new condition of approval.	10/2/2024