VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 12/01/2021; selected revision 03/16/2022

OVERVIEW

Abraxane, 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 Abraxane for conditions listed under "Other Uses with Supportive Evidence". Doses between 100 mg/m^2 and 260 mg/m^2 administered as an intravenous infusion once every 21 days or 28 days are recommended in the product labeling for approved uses.[1]

Guidelines

Abraxane is addressed in a variety of National Comprehensive Cancer Network (NCCN) guidelines:

- **Breast cancer:** Guidelines (version 8.2021 – September 13, 2021) recommend Abraxane 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 (category 1).[2,3] Abraxane, as a single agent, 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 Abraxane may be substituted for paclitaxel or docetaxel due to medical necessity (i.e., hypersensitivity reaction).
- **NSCLC:** Guidelines (version 7.2021 – October 29, 2021) recommend Abraxane 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] Abraxane 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 2.2021 – February 25, 2021) recommend therapy with Abraxane 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 Abraxane for the following conditions: Kaposi sarcoma, intra or extrahepatic cholangiocarcinoma, gallbladder cancer, endometrial carcinoma, melanoma, ovarian/fallopian/primary peritoneal cancer, small bowl adenocarcinoma, and uveal melanoma.[6-13] The criteria are consistent with the guideline recommendations.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Abraxane. 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 Abraxane as well as the monitoring required for adverse events and long-term efficacy, approval requires Abraxane to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Abraxane is recommended in those who meet one of the following criteria:

FDA-Approved Indications

---

1. Breast Cancer. Approve for 1 year if the patient meets the following criteria (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 Abraxane 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.

---

2. Non-Small Cell Lung Cancer (NSCLC). Approve for 1 year if the patient meets the following criteria (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has recurrent or metastatic non-small cell lung cancer (NSCLC); AND
C) Patient meets ONE of the following criteria (i, ii, iii, iv, or v):
- **i.** If the tumor is positive for any of the targetable mutations, at least one of the specific targeted therapy options have been tried; OR
  Note: Examples of targetable mutations are epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, ROS proto-oncogene 1 (*ROS1*).
- **ii.** If the tumor is *BRAF V600E* mutation-positive, *MET* exon 14 skipping mutation-positive, *RET* rearrangement positive, or neurotrophic tyrosine receptor kinase (*NTRK*) gene-fusion positive, Abraxane is used as either first-line or subsequent therapy; OR
- **iii.** If the tumor is *EGFR* exon 20 or *KRAS G12C* mutation positive, Abraxane is used first-line; OR
- **iv.** The NSCLC tumor is negative or unknown for targetable mutations and Abraxane is used as initial therapy; OR
  Note: Examples of targetable mutations are epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, ROS proto-oncogene 1 (*ROS1*) and *BRAF*.
- **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.

---

3. Pancreatic Adenocarcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Abraxane 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

---

4. Biliary Tract Cancer. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has unresectable or metastatic disease; AND
C) Patient has ONE of the following conditions (i, ii, or iii):
- **i.** Gallbladder cancer; OR
- **ii.** Intrahepatic cholangiocarcinoma; OR
- **iii.** Extrahepatic cholangiocarcinoma; AND

D) The medication is used in combination with gemcitabine; AND
E) 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.

---

5. Endometrial Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has metastatic, recurrent, or high-risk 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.

---

6. Kaposi Sarcoma. Approve for 1 year if the patient meets the following criteria (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, 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.

---

7. Melanoma. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has unresectable, advanced 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.

---

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

---

9. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has advanced or metastatic disease; AND
C) If the disease has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H), the patient has progressed on Keytruda (pembrolizumab intravenous infusion) or Opdivo (nivolumab intravenous infusion); AND
D) 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.

---

10. Uveal Melanoma. Approve for 1 year if the patient meets the following criteria (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 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.

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

1. Abraxane® suspension, intravenous infusion [prescribing information]. Summit, NJ: Celgene; August 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 8.2021 – September 13, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 15, 2021.
3. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 15, 2021. Search terms: paclitaxel, albumin bound.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2021 – October 29, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 16, 2021.
5. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2021 – February 25, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
6. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2021 – February 19, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.

7. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 3.2021 – September 9, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
8. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 5.2021 – October 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
9. The NCCN Uveal Melanoma Clinical Practice Guidelines in Oncology (version 2.2021 – June 25, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
10. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2021 – November 4, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
11. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2021 – September 10, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
12. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 5.2021 – September 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
13. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021 – June 7, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2021.
14. Shroff RT, Javle MM, Xiao L, et al. Gemcitabine, cisplatin, and nab-paclitaxel for the treatment of advanced biliary tract cancers. A phase 2 clinical trial. *JAMA Oncol*. 2019;5:824-830.
15. Sahai V, Catalano PJ, Zalupski MM, et al. Nab-paclitaxel and gemcitabine as first-line treatment of advanced or metastatic cholangiocarcinoma. A Phase 2 clinical trial. *JAMA Oncol*. 2018;4:1707-1712.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acquired Immune Deficiency Syndrome (AIDS)-Related Kaposi Sarcoma**: Added new approval condition based on guideline recommendations. **Non-Small Cell Lung Cancer:** Added *MET* exon 14 skipping mutation and *RET* rearrangement-positive, to the list of targetable mutations where Abraxane can be used as initial or subsequent therapy. **Urothelial Carcinoma:** Deleted from policy, since it is no longer supported in guidelines.	11/18/2020
Annual Revision	**Breast Cancer:** A requirement was added that the patient is ≥ 18 years of age. An exception was revised from "Abraxane will be used in combination with Tencentriq" to "will be used in combination with Keytruda" for programmed death-ligand 1 positive, triple-negative breast cancer. Added "Approve up to" verbiage to both dosing regimens. Removed 100 and 150 mg/m^2 doses and revised frequency to "no more than three times in" each 28-day cycle. **Non-Small Cell Lung Cancer:** A requirement was added that the patient is ≥ 18 years of age. Removed non-squamous cell and squamous cell criteria. Removed Abraxane is used as subsequent therapy from exception if the tumor is positive for any of the targetable mutations, at least one of the specific targeted therapy options have been tried. Added exception if the tumor is EGFR exon 20 or KRAS G12C mutation positive, Abraxane is used first line. Removed "either as a single agent or in combination with platinum chemotherapy with or without an immune checkpoint inhibitor" from exception the tumor is negative or unknown for targetable mutations and Abraxane is used as initial therapy. Moved examples of targetable mutations to a Note. Add exception for patients who experience hypersensitivity reactions to paclitaxel or docetaxel. Added "up to" verbiage to dosing regimen and revised frequency to "no more frequently than three times" in each 21 day cycle. **Pancreatic Adenocarcinoma:** A requirement was added that the patient is ≥ 18 years of age. Added "up to" verbiage to dosing regimen and revised frequency to "no more frequently than three times" in each 28 day cycle. **Biliary Tract Cancer:** The condition of approval name was revised from Cholangiocarcinoma (Intra or Extrahepatic). A requirement was added that the patient is ≥ 18 years of age. A requirement was added that the patient has gallbladder cancer, intrahepatic cholangiocarcinoma, or extrahepatic cholangiocarcinoma. **Endometrial Carcinoma:** A requirement was added that the patient is ≥ 18 years of age. **Kaposi Sarcoma:** Acquired Immune Deficiency Syndrome (AIDS) Related was removed from the condition of approval. A requirement was added that the patient is ≥ 18 years of age. Revised dosing frequency to no more frequently than three times.	12/01/2021

	Melanoma: A requirement was added that the patient is ≥ 18 years of age. Revised dosing frequency to no more frequently than three times. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:** A requirement was added that the patient is ≥ 18 years of age. Added Approve up to verbiage to both dosing regimens. Added "Approve up to" verbiage to both dosing regimens. Revised frequency to "no more than three times in" each 28-day cycle. **Small Bowel Adenocarcinoma:** A requirement was added that the patient is ≥ 18 years of age. Added "Approve up to" verbiage to both dosing regimens. Revised frequency to "no more than three times in" each 28-day cycle. **Uveal Melanoma:** A requirement was added that the patient is ≥ 18 years of age.	
Selected Revision	**Biliary Tract Cancer:** Revised dosing to up to 125 mg/m^2 given no more frequently than twice every 21 days, or no more frequently than three times every 28 days. Previously was 100 to 260 mg/m^2 administered no more frequently than once every 21 days.	03/16/2022