

Paclitaxel Protein Bound (Abraxane)

Effective Date: 7/1/23

Revision Date(s): 9/17/21

Review Date: 4/22/22

Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria

Ampullary Adenocarcinoma

- Used in combination with gemcitabine as:
 - Neoadjuvant therapy; **OR**
 - For unresectable or metastatic disease

Breast Cancer

- The member has recurrent, unresectable, or metastatic disease; **AND**
 - Used as a single agent or in combination with carboplatin for HER-2 negative disease; **OR**
 - The member has PD-L1 positive and triple negative disease; **AND**
 - Used in combination with pembrolizumab; **OR**
 - Used in combination with trastuzumab as third-line therapy and beyond for HER-2 positive disease

Hepatobiliary Cancers

- The member has unresectable or metastatic disease; **AND**
- Used in combination with gemcitabine

Kaposi Sarcoma

- Used as a single agent as subsequent therapy

Melanoma – Cutaneous

- The member has metastatic or unresectable disease; **AND**

- Used as subsequent therapy after disease progression or maximum clinical benefit from BRAF-targeted therapy; **AND**
 - Used in combination with carboplatin; **OR**
 - Used as a single agent

Melanoma – Uveal

- Used as a single agent for distant metastatic disease

Non-Small Cell Lung Cancer (NSCLC), locally advanced, recurrent, or metastatic

- Use of Abraxane in the first-line setting:
 - The member has no actionable biomarkers (e.g., EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET and RET)¹; **AND**
 - Used in combination with atezolizumab and carboplatin
 - For non-squamous histology; **OR**
 - Used in combination with pembrolizumab and carboplatin
 - For squamous histology; **OR**
 - Used in combination with carboplatin; **OR**
 - Used as a single agent
- Use of Abraxane in the subsequent line setting:
 - The member has no actionable biomarkers (e.g., EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET and RET)¹; **AND**
 - Used in combination with atezolizumab and carboplatin; **AND**
 - For non-squamous histology; **OR**
 - Used in combination with pembrolizumab and carboplatin; **AND**
 - For squamous histology; **OR**
 - Used in combination with carboplatin; **OR**
 - Used as a single agent; **OR**
 - The member's tumor has actionable biomarkers:
 - The member has progressed on or after receiving targeted therapy; **AND**
 - Used in combination with atezolizumab and carboplatin for non-squamous histology; **OR**
 - Used in combination with pembrolizumab and carboplatin for squamous histology; **OR**
 - Used in combination with carboplatin; **OR**
 - Used as a single agent

Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

- As subsequent therapy; **AND**
 - As a single agent; **OR**
 - Used in combination with carboplatin for patients with confirmed taxane hypersensitivity

¹ If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.

Pancreatic cancer

- Used in combination with gemcitabine for either;
 - Locally advanced disease in the neoadjuvant setting; **OR**
 - Metastatic disease

Small Bowel Adenocarcinoma

- The member has advanced or metastatic disease; **AND**
 - Used as a single agent; **OR**
 - Used in combination with gemcitabine

Uterine Neoplasms

- As a single agent; **AND**
 - Used as adjuvant therapy for stage III-IV disease; **OR**
 - Used for recurrent or metastatic disease

Billing

Drug Name	HCPCS Code	Description
Abraxane	J9264	Inj., nab-paclitaxel, 1 mg
Abraxane, generic	J9259	Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to J9264, 1 mg

References

1. Abraxane. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 4/28/2022
2. Abraxane [package insert]. Abraxis BioScience, LLC, Summit, NJ. Available at: https://packageinserts.bms.com/pi/pi_abraxane.pdf
3. Ampullary Adenocarcinoma. NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf. Accessed 4/28/22
4. Breast Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed 4/28/22
5. Hepatobiliary Cancers: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed 4/28/22
6. Kaposi Sarcoma: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kaposi.pdf. Accessed 4/28/22
7. Melanoma Cutaneous: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed 4/28/22
8. Melanoma Uveal: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf. Accessed 4/28/22
9. Non-Small Cell Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 4/28/22

10. Ovarian Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed 4/28/22
11. Pancreatic Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed 4/28/22
12. Small Bowel Adenocarcinoma: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf. Accessed 4/28/22
13. Uterine Neoplasms: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed 4/28/22

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.