Medical Drug Clinical Criteria

Subject:	Abraxane (paclitaxel, protein bound)		
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Overview

This document addresses the use of protein/albumin bound paclitaxel (Abraxane). Abraxane is a taxane primarily used to treat breast cancer, pancreatic cancer, and non-small cell lung cancer.

The FDA approved indications for Abraxane include:

- Metastatic breast cancer after failure of combination chemotherapy
- Non-small cell lung cancer (NSCLC) as first line treatment of locally advanced or metastatic NSCLC in combination with carboplatin
- Adenocarcinoma of the pancreas as first line therapy of metastatic disease in combination with gemcitabine

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 1 or 2A level of evidence for the following:

- Hypersensitivity to solvent based taxanes
  - Use in the treatment of taxane responsive cancers when there is incidence of solvent-based taxane hypersensitivity including in NSCLC, endometrial cancers, breast cancers and solid tumors
- Melanoma
  - Use in as a single or in combination with carboplatin in malignant melanoma when used as second line or subsequent therapy
- Pancreatic cancer
  - Use in combination with gemcitabine and cisplatin in locally advanced or metastatic pancreatic cancer when used as first-line therapy or continuation therapy
- NSCLC
  - Use for locally advanced or metastatic NSCLC in combination with carboplatin and pembrolizumab or atezolizumab.
  - Recurrent, advanced, or metastatic disease in squamous NSCLC tremelimumab-actl, durvalumab, and carboplatin
- Ovarian cancer
  - Use for ovarian cancer in the treatment of persistent or recurrent ovarian cancer
- Breast cancer
  - Use as a third-line agent in combination with trastuzumab in HER2-positive recurrent unresectable or stage IV disease
- Ampullary adenocarcinoma
  - Use as first-line agent in metastatic ampullary adenocarcinoma specifically for pancreatobiliary/mixed type in combination with gemcitabine
  - Use as subsequent therapy in those with ECOG score of 0 to 1 in combination with gemcitabine
- Use as a single agent or in combination with gemcitabine for advanced or metastatic small bowel adenocarcinoma as
  - initial therapy or
  - as subsequent therapy in those who previously received initial therapy with a PD-1 inhibitor (nivolumab with or without ipilimumab, pembrolizumab, or dostarlimab-gxly) (Aldrich, 2018; Overman, 2018)

Abraxane label includes a black box warning restricting use in patients with baseline neutrophil counts of less than 1,500 cells/mm^3, and frequent peripheral blood cell counts should be performed to monitor for bone marrow suppression.

Other Uses

Protein-bound paclitaxel has been studied or is currently being studied as a single agent or in combination with other chemotherapeutic agents for the treatment of other cancers, including use in adrenocortical cancer (Demeure, 2012), advanced solid tumors (Abu-Khalaf, 2015), angiosarcoma (Hirata, 2011), cancer of unknown primary (CUP), cervical cancer (Alberts, 2012; Li, 2017), esophageal cancer (Fan, 2016; Shi, 2013), gastric cancer (Koizumi, 2015), head and neck cancer (including squamous-cell carcinoma of the esophagus, hypopharynx, nasopharyngeal, oropharynx, and oral cavity) (Adkins, 2013; Adkins, 2016; Damascelli, 2007; Huang, 2016), hepatocellular cancer, cholangiocarcinoma (Sahai 2018), prostate cancer (Shepard, 2009), small cell lung cancer (Grilley-Olson, 2015), urothelial cancer (Ko, 2013), and AIDS-related Kaposi Sarcoma (Fortino, 2016). Limitations of some of these studies include lack of a randomized comparator group and small study populations.

To date, the FDA has not approved protein-bound paclitaxel for use in the treatment of any of these conditions. NCCN also gives a category 2A recommendation for use of Abraxane in combination with atezolizumab, carboplatin, and with or without bevacizumab as first line therapy in those with NSCLC and BRAF or NTRK positive tumors in certain circumstances, however, published data is lacking. Additionally, the NCCN NSCLC guideline discussion emphasizes the importance of targeted therapies in individuals with specific oncogenic drivers (i.e., EGFR, ALK, ROS1, BRAF, NTRK).

Additionally protein-bound paclitaxel received 2A recommendations for use in invasive inflammatory and special consideration breast cancer.. NCCN Breast cancer guidelines support for this use followed that sequential single agents are preferred but chemotherapy combinations may be used in select individuals with high tumor burden, rapidly progressing disease and visceral crisis. At this time there is no evidence to directly support the use of Abraxane plus carboplatin in this population.

Abraxane also received a recommendation for use as a second-line or subsequent therapy as a single agent for cervical cancer, as local/regional recurrence, stage IVB or distant metastases, or persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC). NCCN previously provided a 2B recommendation for this use, but updated their compendia to 2A. NCCN cited the same data (Alberts 2012 trial) an open-label phase 2 study which enrolled 35 patients. The study included those with persistent or recurrent carcinoma of the cervix with disease progression and treated them with Abraxane. The overall survival was 9.4 months and progression-free survival was 5 months. Twenty-five patients discontinued due to disease progression.

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Adjuvant therapy: Treatment given after the primary treatment to increase the chances of a cure; may include chemotherapy, radiation, hormone or biological therapy.

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Melanoma: A type of cancer that begins in the melanocytes. Melanoma is also referred to as malignant melanoma and cutaneous melanoma.

Microtubule inhibitors (MTI): A class of drugs including taxanes, vinca alkaloids, and epothilones that stabilize or destabilize microtubules, thereby suppressing microtubule dynamics required for proper mitotic function, effectively blocking cell cycle progression and resulting in cell death.

Non-small cell lung cancer: A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. The three main types of non-small cell lung cancer are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma.

One line of therapy: Single line of therapy.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place

in the body.

Taxane: A type of mitotic inhibitor and antimicrotubule drug used to treat cancer that blocks cell growth by stopping mitosis (cell division).

Unresectable: Unable to be removed with surgery.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Abraxane (paclitaxel, protein bound)

Requests for Abraxane (paclitaxel, protein bound) may be approved for the treatment of any of the following indications:

I. Relapsed or metastatic breast cancer when the following criteria are met (NCCN 2A):
   A. Used as a single agent; **AND**
   B. Used in a single line of therapy;

OR

II. Metastatic or unresectable locally advanced breast cancer when the following criteria are met (NCCN 1):
   A. Individual has triple-negative breast cancer, defined as lack of estrogen- and progesterone-receptor expression and no overexpression of HER2; **AND**
   B. Individual is using in combination with pembrolizumab;

OR

III. Treatment of any breast cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

IV. Malignant Melanoma when the following criteria are met (NCCN 2A):
   A. Used as
      1. A single agent; **OR**
      2. In combination with carboplatin;

      AND
   B. Individual is using as second line or subsequent therapy; **AND**
   C. Individual has an ECOG performance status of 0-2 (Kottschade 2011);

OR

V. Treatment of recurrent, locally advanced or metastatic NSCLC when the following criteria are met (Label):
   A. Used as first-line therapy; **AND**
   B. Given in combination with carboplatin; **AND**
   C. Individual has an ECOG performance status of 0-2 (NCCN 2A);

OR

VI. Treatment of recurrent, advanced, or metastatic NSCLC when the following criteria are met (NCCN 2A):
   A. Used as a single agent for first progression after initial systemic therapy (if not already given); **AND**
   B. Individual has an ECOG performance status of 0-2;

OR

VII. Treatment of recurrent, advanced or metastatic squamous NSCLC when **all** of the following criteria are met (NCCN 1, 2A):
   A. Used as first-line therapy; **AND**
   B. Given in combination with pembrolizumab and carboplatin; **AND**
   C. Individual has a current ECOG performance status of 0-2;

OR

VIII. Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 2A):
   A. Used as first-line therapy; **AND**
   B. Given in combination with atezolizumab and carboplatin; **AND**
   C. Individual has an ECOG performance status of 0-2;

OR

IX. Treatment of recurrent, advanced, or metastatic squamous NSCLC when the following criteria are met (NCCN 2A):
   A. Used as first line therapy; **AND**
   B. Individual has no sensitizing epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genetic tumor aberrations; **AND**

C. Individual is using in combination with tremelimumab-actl, durvalumab, and carboplatin; **AND**
D. Individual has a PD-L1 expression ≥ 1% and less than or equal to 49%; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
F. Individual has an ECOG performance status of 0-2;

OR

X. Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 1, 2A):
A. Used as subsequent therapy after failure of kinase inhibitor targeted agent; **AND**
B. Given in combination with carboplatin and atezolizumab; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

XI. Treatment of NSCLC in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XII. Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) when the following criteria are met (NCCN 2A):
A. Treatment of persistent or recurrent ovarian cancer when used as a single agent (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer); **OR**
B. Treatment of persistent or recurrent ovarian cancer when used with carboplatin (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) in an individual with confirmed taxane (that is, solvent-base paclitaxel or docetaxel) hypersensitivity;

OR

XIII. Locally advanced or metastatic adenocarcinoma of the pancreas when the following criteria are met (Label, NCCN 1, 2A):
A. Used as first-line therapy or as continuation (maintenance therapy); **AND**
B. Given in combination in one of the following ways:
1. With gemcitabine as a single-line of therapy; **OR**
2. With gemcitabine and cisplatin;

OR

XIV. Recurrent, metastatic, or high-risk endometrial cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XV. Solid tumors where treatment with a taxane is medically appropriate and the individual has confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XVI. Advanced or metastatic Small bowel adenocarcinoma, when the following criteria are met (NCCN 2A):
A. Treatment of advanced or metastatic disease; **AND**
B. Given in combination with gemcitabine;

OR

XVII. Ampullary adenocarcinoma, when the following criteria are met (NCCN 2A):
A. Treatment in pancreatobiliary and mixed type disease; **AND**
B. Given in combination with gemcitabine; **AND**
C. Individual has an ECOG performance status of 0-2.

Abraxane (paclitaxel, protein bound) may not be approved for the following:

I. Individual has baseline neutrophil count of less than 1,500 cells/mm^3 prior to initiation of Abraxane; **OR**
II. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9264	Injection, paclitaxel protein-bound particles, 1 mg [Abraxane]

J9259	Injection, paclitaxel protein-bound particles (American Regent)

ICD-10 Diagnosis

C00.0-C80.2	Malignant neoplasms
C17.0-C17.9	Malignant neoplasm of small intestine
C24.1	Malignant neoplasm of ampulla of Vater
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C50.011-C50.929	Malignant neoplasm of breast
C54.0-C54.9	Malignant neoplasm of endometrium
C56.1-C56.9	Malignant neoplasm of ovary
D00.00-D09.9	In-situ neoplasms
Z85.00-Z85.59	Personal history of malignant neoplasm
Z85.810-Z85.9	Personal history of malignant neoplasm

Document History

Revised: 02/24/2023
Document History:

- 02/24/2023 – Annual review: Update existing criteria for use in malignant melanoma and pancreatic cancer from NCCN. Added 2A NCCN criteria for use in small bowel adenocarcinoma, ampullary adenocarcinoma, and recurrent, advanced, or metastatic squamous NSCLC in combination with tremelimumab-actl, durvalumab, and carboplatin. Coding Reviewed: Added HCPCS J9259. Added ICD-10-CM C17.0-C17.9, C24.1.
- 02/25/2022 – Annual review: Update NSCLC criteria with NCCN recommendations. Update references. Coding Reviewed: No changes.
- 09/13/2021 – Select review: Update criteria to remove use with atezolizumab for triple negative breast cancer per FDA withdrawal. Coding reviewed: Extended ICD-10-CM code ranges C34.00-C34.92, C50.011-C50.929, C54.0-C54.9, C56.1-C56.9.
- 05/21/2021 – Select review: Update criteria to allow for use with pembrolizumab for triple negative breast cancer per NCCN. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: Update NSCLC criteria for use in combination with pembrolizumab and carboplatin. Remove notation regarding confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown in NSCLC criteria for consistency. Update references. Coding Reviewed: No changes.
- 05/15/2020 – Select Review: Update NSCLC criteria to include first-line therapy use in recurrent and advanced disease, and confirmation of negative ROS1 and BRAF mutations when using in combination with atezolizumab and carboplatin. Add criteria to allow use as subsequent therapy in NSCLC after failure of targeted agents. Coding reviewed: No changes.
- 02/21/2020 – Annual Review: Update NSCLC criteria to remove use with cisplatin per NCCN update. Update ovarian cancer criteria to add use with carboplatin if individual has solvent-base paclitaxel or docetaxel hypersensitivity. Add baseline neutrophil count threshold in non-approvable criteria per labeled contraindications. Wording and formatting changes. Coding Review: No changes.
- 12/09/2019 – Select Review: Add criteria for metastatic nonsquamous NSCLC in combination with atezolizumab and carboplatin. Coding reviewed: Added ICD-10 DX C34.0-C56.9
- 08/16/2019 – Select Review: Update to clarify single agent use in ovarian cancer. Wording and formatting changes for consistency. Coding Reviewed: No changes.
- 05/17/2019 – Annual Review: Initial review of protein bound paclitaxel (Abraxane); Updated to clarify that use in combination with pembrolizumab for the treatment of NSCLC required that the individual also meet the criteria for pembrolizumab. Coding Reviewed: No changes.

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    a. Ampullary adenocarcinoma. V2.2022. Revised December 6, 2022.
    b. Breast cancer. V4.2022. Revised June 21, 2022
    c. Cervical Cancer V1.2023. Revised December 23, 2022.
    d. Cutaneous Melanoma. V1.2023. Revised December 22, 2022.
    e. Hepatobiliary Cancers. V4.2022. Revised December 9, 2022.
    f. Kaposi Sarcoma. V1.2023. Revised December 20, 2022.
    g. Non-Small cell lung cancer. V1.2023. Revised December 22, 2022.
    h. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V1.2023. Revised December 22, 2022.
    i. Pancreatic Adenocarcinoma. V2.2022. Revised December 6, 2022.
    j. Small Bowel Adenocarcinoma. V2.2022. Revised October 27, 2022.
    k. Uterine Neoplasms. V1.2023. Revised December 22, 2022.
    l. Uveal melanoma. V2.2022. Revised April 5, 2022.
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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.