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 or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Non-small cell lung cancer (NSCLC) as first line treatment of locally advanced or metastatic NSCLC in combination with carboplatin in those who are not candidates for curative surgery or radiation therapy.
- 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 (including Kaposi sarcoma, ovarian cancer including epithelial, ovarian, fallopian tube, and primary peritoneal cancer)
- Melanoma (Uveal or cutaneous)
  - Use as single agent therapy for metastatic or unresectable disease
  - Second-line therapy or subsequent therapy as single agent or in combination with carboplatin for metastatic or unresectable disease
- Pancreatic cancer
  - Use in combination with gemcitabine and cisplatin, but not after resection, in locally advanced or metastatic pancreatic cancer when used as first-line therapy, subsequent therapy, or continuation therapy
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- Kaposi Sarcoma
  - Use for relapsed/refractory disease as a single agent for subsequent systemic therapy.
- NSCLC
  - Systemic therapy:
    - For recurrent, advanced, or metastatic disease with ECOG 0-1 and no contraindications to PD-1 or PD-L1 inhibitors in combination with atezolizumab and carboplatin for nonsquamous histology, carboplatin and pembrolizumab for squamous histology, or tremelimumab-actl, durvalumab, and carboplatin.
    - For recurrent, advanced, or metastatic disease as first-line therapy for PD-L1 expression tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2 in combination with pembrolizumab and carboplatin for squamous histology, in combination with carboplatin and atezolizumab for nonsquamous histology, or in combination with tremelimumab-actl, durvalumab, and carboplatin for squamous histology.
    - Treatment for recurrent, advanced, or metastatic disease
      - In combination with carboplatin (PS 0-2)

- As single agent for PS 2 or subsequent therapy (if not already given)

- Ovarian cancer
  - Use for ovarian cancer in the treatment of persistent or recurrent unresectable ovarian cancer

- Cervical cancer
  - Second-line or subsequent therapy as a single agent for unresectable local/regional recurrence, stage IVB or recurrence, or persistent, recurrent, or metastatic small NECC (cell neuroendocrine carcinoma of the cervix)
- Biliary tract cancers
  - Primary or subsequent treatment in combination with gemcitabine for unresectable or R2 (resected gross residual) disease or metastatic disease
- Breast cancer
  - First-line therapy in combination with pembrolizumab or second line/subsequent therapy (if PD-1/PD-L1 inhibitor has not been previously used) for PD-L1 positive triple negative recurrent unresectable or stage IV disease.
  - First-line therapy (if no germline BRCA 1/2 mutation), second line (if not a candidate for fam trastuzumab deruxtecan-nxki), or third line therapy as single agent therapy or in combination with carboplatin for recurrent unresectable, or stage IV HER2-negative HR+ with visceral crisis or endocrine therapy refractory disease.
  - First line therapy (if no germline BRCA 1/2 mutation and if PD-L1 CPS < 10), second line therapy, or third-line therapy as single agent therapy or in combination with carboplatin for recurrent unresectable, or stage IV triple negative breast cancer.
  - Fourth-line therapy and beyond in combination with trastuzumab for HER2-positive recurrent unresectable or stage IV that is HR negative or HR positive with or without endocrine therapy.
  - May be substituted for other taxanes (paclitaxel or docetaxel) in select patients due to medical necessity (ie, hypersensitivity reaction)

- Uterine /Endometrial Carcinoma/Vaginal Cancer
  - Second-line or subsequent therapy as a single agent for recurrent disease.
- Ampullary adenocarcinoma
  - Use as first-line agent in metastatic ampullary adenocarcinoma specifically for pancreatobiliary/mixed type in combination with gemcitabine if ECOG status 0-2
  - Use as subsequent therapy in those with ECOG score of 0 to 1 in combination with gemcitabine for pancreatobiliary/mixed type disease.
- Small Bowel adenocarcinoma
  - 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)
- Vaginal cancer
    - Second-line or subsequent therapy as a single agent for local/regional recurrence, stage IVB or recurrent distant metastases.

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.

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.

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.

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).

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. Individual has a diagnosis of Breast Cancer; **AND**
   A. Individual is using as a single agent after failure on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy (Label); **AND**
      1. Individual has had previous chemotherapy including an anthracycline unless clinically contraindicated;

   OR

   B. Individual has recurrent unresectable or metastatic (stage IV) disease; **AND**
      1. Individual has HER2 negative disease (NCCN 2A): **AND**
         a. Individual is using as a single agent or in combination with carboplatin; **AND**
         b. Disease is hormone receptor-positive and refractory to endocrine therapy or has visceral crisis; **AND**
         c. Using in one of the following ways:
            i. First line therapy if no germline BRCA 1/2 mutation; **OR**
            ii. Second-line therapy if not a candidate for fam trastuzumab deruxtecan-nxki; **OR**
            iii. Third-line therapy and beyond;

      OR

      2. Individual has triple negative breast cancer (NCCN 2A); **AND**
         a. Individual has disease with high tumor burden, rapidly progressing disease and visceral crisis; **AND**
         b. Individual is using as a single agent or in combination with carboplatin; **AND**
         c. Using in one of the following ways:
            i. First line therapy if PD-L1 < 10 and no germline BRCA 1/2 mutation; **OR**
            ii. Second-line therapy and beyond;

         OR

         d. Individual has PD-L1 positive, triple-negative disease; **AND**
            i. Individual is using in combination with pembrolizumab; **AND**

ii. Using in one of the following ways:
(a). As first line therapy (NCCN 1); **OR**
(b). Second and subsequent line of therapy if PD-1/PD-L1 inhibitor has no been previously used (NCCN 2A);

OR

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

OR

II. Individual has a diagnosis of recurrent unresectable or metastatic cervical cancer (NCCN 2A); **AND**
A. Individual is using as second-line or subsequent therapy; **AND**
B. Individual is using as a single agent;

OR

III. Individual has a diagnosis of Malignant Melanoma (NCCN 2A); **AND**
A. Individual is using in one of the following ways:
1. As 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

IV. Individual has a diagnosis of Kaposi Sarcoma (NCCN 2A); **AND**
A. Individual has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**
B. Individual is using as subsequent systemic therapy; **AND**
C. Individual is using as a single agent;

OR

V. Individual has a diagnosis of recurrent, locally advanced or metastatic NSCLC (Label, NCCN 1); **AND**
A. Individual is using as first-line therapy; **AND**
B. Individual is using in combination with carboplatin; **AND**
C. Individual has an ECOG performance status of 0-2 (NCCN 2A);

OR

VI. Individual has a diagnosis of recurrent, advanced, or metastatic NSCLC (NCCN 2A); **AND**
A. Individual is using 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. Individual has a diagnosis of recurrent, advanced or metastatic squamous NSCLC (NCCN 1, 2A); **AND**
A. Individual is using as first-line therapy; **AND**
B. Individual is using in combination with pembrolizumab and carboplatin; **AND**
C. Individual has a crrent ECOG performance status of 0-2;

OR

VIII. Individual has a diagnosis of recurrent, advanced, or metastatic nonsquamous NSCLC (NCCN 2A):
A. Individual is using as first-line therapy; **AND**
B. Individual is using in combination with atezolizumab and carboplatin; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

IX. Individual has a diagnosis of recurrent, advanced, or metastatic nonsquamous NSCLC (NCCN 1, 2A); **AND**
A. Individual is using as subsequent therapy after failure of kinase inhibitor targeted agent; **AND**
B. Individual is using in combination with carboplatin and atezolizumab; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

X. Individual has a diagnosis of recurrent, advanced, or metastatic squamous NSCLC (NCCN 2A); **AND**
A. Individual is using 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

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

OR

XII. Individual has a diagnosis Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) (NCCN 1, 2A); **AND**
A. Individual is using for 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. Individual is using for the 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. Individual has a diagnosis of metastatic adenocarcinoma of the pancreas (Label, NCCN 1, 2A); **AND**
A. Individual is using as first line therapy; **AND**
B. Individual is using 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. Individual has a diagnosis of locally advanced adenocarcinoma of the pancreas (NCCN 2A); **AND**
A. Individual is using as first-line therapy, subsequent therapy, or as continuation (maintenance therapy); **AND**
B. Individual is using in combination with gemcitabine as a single-line of therapy;

OR

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

OR

XVI. Individual has a diagnosis of locally advanced recurrent or metastatic vaginal cancer (NCCN 2A); **AND**
A. Individual is using as second-line or subsequent therapy; **AND**
B. Individual is using as a single agent;

OR

XVII. 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

XVIII. Individual has a diagnosis of small bowel adenocarcinoma (NCCN 2A); **AND**
A. Individual has advanced or metastatic disease; **AND**
B. Individual is using as a single agent or in combination with gemcitabine;

OR

XIX. Individual has a diagnosis of ampullary adenocarcinoma (NCCN 2A); **AND**
A. Individual is using in pancreatobiliary and mixed type disease; **AND**
B. Individual is using in combination with gemcitabine; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

XX. Individual has a diagnosis of Biliary Tract Cancer (NCCN 2A); **AND**
   A. Individual is using in unresectable or resected gross residual disease OR metastatic disease; **AND**
   B. Individual is using in combination with gemcitabine.

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]

ICD-10 Diagnosis

C17.0-C17.9	Malignant neoplasm of small intestine
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0-C24.9	Malignant neoplasm of other and unspecified parts of biliary tract
C25.0-C25.9	Malignant neoplasm of pancreas
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C43.0-C43.9	Malignant melanoma of skin
C46.0-C46.9	Kaposi's sarcoma
C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C50.011-C50.929	Malignant neoplasm of breast
C52	Malignant neoplasm of vagina
C53.0-C53.9	Malignant neoplasm of cervix uteri
C54.0-C54.9	Malignant neoplasm of endometrium
C55	Malignant neoplasm of uterus, part unspecified
C56.1-C56.9	Malignant neoplasm of ovary
C57.00-C57.9	Malignant neoplasm of other and unspecified female genital organs
C69.30-C69.32	Malignant neoplasm of choroid
C69.40-C69.42	Malignant neoplasm of ciliary body
Z85.00-Z85.59	Personal history of malignant neoplasm
Z85.810-Z85.9	Personal history of malignant neoplasm

Document History

Revised: 02/21/2025
Document History:

- 02/21/2025 – Annual Review: Add NCCN 2A Kaposi Sarcoma for relapsed/refractory disease as a single agent for subsequent systemic therapy. Add NCCN 2A Vaginal Cancer for use in locally advanced recurrent or metastatic disease as a single agent for second-line or subsequent therapy. Clarify NCCN recommendation for use in cervical cancer in recurrent unresectable disease. Update NCCN 2A recommendation for use in pancreatic cancer as subsequent therapy in addition to first-line and continuation. Wording and formatting updates. Coding Reviewed: Removed ICD-10-CM range C00.0-C80.2, leaving only C17.0-C17.9, C22.1, C23, C24.0-C24.9, C25.0-C25.9, C33, C34.00-C34.92, C43.0-C43.9, C46.0-C46.9, C48.0-C48.8, C50.011-C50.929, C52, C53.0-C53.9, C54.0-C54.9, C55, C56.1-C56.9, C57.00-C57.9, C69.30-C69.32, C69.40-C69.42. Removed ICD-10-CM D00.0-D09.9. 11/25/24 – CMS Coding Update: Removed HCPCS J9258 and J9259.
- 02/23/2024 – Annual review: Update existing criteria for use in breast cancer, pancreatic cancer, and small bowel adenocarcinoma. Add NCCN 2A criteria for use in unresectable or metastatic biliary tract cancer when used in combination with gemcitabine. Add NCCN 2A recommendation for use in cervical cancer as second-line or subsequent therapy in recurrent or metastatic disease. Coding Reviewed: Added HCPCS J9258.
- 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.

References

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    a. Ampullary adenocarcinoma. V2.2025. Revised January 10, 2025.
    b. Breast Cancer. V6.2024. Revised November 11, 2024.
    c. Biliary Tract Cancers. V6.2024. Revised January 10, 2024.
    d. Cervical Cancer. V1.2025. Revised December 19, 2024.
    e. Cutaneous Melanoma. V1.2025. December 20. 2024.
    f. Kaposi Sarcoma. V2.2025. Revised January 14, 2025.
    g. Non-Small Cell Lung Cancer. V3.2025. Revised January 14, 2025.
    h. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V3.2024. Revised July 15, 2024.
    i. Pancreatic Adenocarcinoma. V1.2025. Revised December 20, 2024.
    j. Small Bowel Adenocarcinoma. V1.2025. Revised December 4, 2024.
    k. Uterine neoplasms. V1.2025. Revised December 16, 2024.
    l. Uveal Melanoma. V1.2024. Revised May 23, 2024.
    m. Vaginal Cancer V3.2025. Revised December 16, 2024.
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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.