Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Paclitaxel Albumin, Protein Bound (Abraxane®)	MP-RX-FP-69-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	2/22/2026
			Last Review Date:	Frequently Revision:
			2/22/2026	2/22/2027

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description:

This document addresses the use of Paclitaxel Albumin/Protein Bound (Abraxane®), a taxane primarily used to certain patients with advanced (metastatic) breast cancer, advanced (metastatic) pancreatic cancer, and advanced non-small cell lung cancer.

Background Information:

Abraxane [nano-particle albumin bound (nab) paclitaxel] is an antimicrotubule agent that functions by stimulating the formation of microtubules from tubulin dimers and maintaining the stability of microtubules to prevent their breakdown. This stability disrupts the regular dynamic reorganization of microtubules, which is crucial for various essential cellular functions during interphase and mitosis.

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
  - 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

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- 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 or continuation therapy
- 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 ovarian cancer
- Cervical cancer:
  - Second-line or subsequent therapy as a single agent for local/regional recurrence, stage IVB or recurrence, or persistent, recurrent, or metastatic small NECC (cell neuroendocrine carcinoma of the cervix)
- Billiary tract cancer
  - 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.

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- 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
  - 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. It also has the following warnings and precautions:

- Sensory neuropathy
- Risk of sepsis: There's a potential for sepsis, with or without neutropenia, when Abraxane is used in conjunction with gemcitabine.
- Pneumonitis risk: When administered with gemcitabine, there is a risk of pneumonitis.
- Severe hypersensitivity reactions
- Hepatic impairment: Patients with hepatic impairment may exhibit increased exposure and toxicity to paclitaxel. It is advisable to consider dose reduction and closely monitor.
- Viral transmission risk: Abraxane contains albumin derived from human blood, which carries a theoretical risk of viral transmission (Celgene, 2020).

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

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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.

Please note that the albumin-bound form of paclitaxel can significantly affect the drug's functional properties compared to its soluble form. Therefore, it should not be substituted for or used in conjunction with other paclitaxel formulations.

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.

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    - 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.

Approved Indications

A. See Background section above

Other Uses

A. 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.
B. 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

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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).

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
C00.0-C80.2	Malignant neoplasms
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
C24.1	Malignant neoplasm of ampulla of Vater
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
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
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

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Medical Necessity Guidelines:

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Paclitaxel Albumin, Protein Bound (Abraxane®)

A. Criteria For Initial Approval (Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)

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**

A. 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 and beyond;

OR

B. Individual has triple negative breast cancer (NCCN 2A); **AND**

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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:
      1. As first line therapy (NCCN 1);

      OR

      2. Second and subsequent line of therapy if PD-1/PD-L1 inhibitor has not 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*** when the following criteria are met (NCCN 2A):
   A. Individual is using in one of the following ways:
      1. A single agent;

      OR

      2. In combination with carboplatin; **AND**
   B. Individual is using as second line or subsequent therapy; **AND**

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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. 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. Individual has a diagnosis of recurrent, advanced, or metastatic ***NSCLC*** (NCCN 2A); **AND**
   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. Individual has a diagnosis of recurrent, advanced or metastatic squamous ***NSCLC*** (NCCN 1, 2A); **AND**
   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. Individual has a diagnosis of recurrent, advanced, or metastatic squamous ***NSCLC*** (NCCN 2A); **AND**
   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. Individual has a diagnosis of recurrent, advanced, or metastatic squamous ***NSCLC*** (NCCN 2A); **AND**
   A. Used as first line therapy; **AND**

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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. Individual has a diagnosis of recurrent, advanced, or metastatic nonsquamous ***NSCLC*** (NCCN 1, 2A); **AND**
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. Individual has a diagnosis of ***Ovarian Cancer*** (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) when the following criteria are met (NCCN 1, 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. Individual has a diagnosis of locally advanced or metastatic ***adenocarcinoma of the pancreas*** when the following criteria are met (Label, NCCN 1, 2A):
A. Used as first-line therapy; **AND**
B. Given in combination in one of the following ways:
1. With gemcitabine as a single-line of therapy;

OR

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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 or as continuation (maintenance therapy); **AND**
   B. Individual is using in combination with gemcitabine as a single-line of therapy;

OR

xv. Individual has a diagnosis of recurrent, metastatic, or high-risk ***endometrial cancer*** 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. Individual has a diagnosis of ***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.

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B. Criteria For Continuation of Therapy

i. MMM considers continuation of Paclitaxel Albumin, Protein Bound (Abraxane®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: 6 months

ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

A. Individual has baseline neutrophil count of less than 1,500 cells/mm3 prior to initiation of Abraxane;

OR

B. When the above criteria (section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

FDA Approved Indication	Recommended Dose Regimen	Recommended Duration
Metastatic Breast Cancer	• 260 mg/m^2 i.v. over 30 minutes every 3 weeks	Until disease progression or unacceptable toxicity.
Non-Small Cell Lung Cancer	• 100 mg/m^2 i.v. on days 1, 8, and 15 of each 21-day cycle. Administer carboplatin on Day 1 of each 21-day cycle.	Until disease progression or unacceptable toxicity.
Adenocarcinoma of the Pancreas	• 125 mg/m^2 i.v. on days 1, 8, and 15 of each 28-day cycle. Administer gemcitabine on Days 1, 8, and 15 of each 28-day cycle.	Until disease progression or unacceptable toxicity.

Exceptions
• ABRAXANE is not recommended for use in patients with AST >10 x ULN; or bilirubin >5 x ULN or with metastatic adenocarcinoma of the pancreas who have moderate to severe hepatic impairment. • For MBC or NSCLC, reduce starting dose in patients with moderate to severe hepatic impairment. • Dose reductions or discontinuation may be needed based on severe hematologic, neurologic, cutaneous, or gastrointestinal toxicities.

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    b. Breast cancer. V5.2023. Revised December 5, 2023.
    c. Biliary Tract Cancers. V3.2023. Revised November 8, 2023.
    d. Cervical Cancer V1.2024. Revised September 20, 2023.
    e. Cutaneous Melanoma. V3.2023. Revised October 27, 2023.
    f. Kaposi Sarcoma. V1.2024. Revised November 7, 2023.
    g. Non-Small cell lung cancer. V1.2024. Revised December 21, 2023
    h. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V2.2023. Revised June 2, 2023 i
    i. Pancreatic Adenocarcinoma. V1.2024. Revised December 13, 2023.
    j. Small Bowel Adenocarcinoma. V1.2024. Revised December 20, 2023.
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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.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.			
Annual Review	Updated product name to include albumin. Added diagnoses for Kaposi Sarcoma and Vaginal Cancer to Background Information. Coding Reviewed: added ICD10: C57.00-C57.9, C69.40-C69.42; removed duplicate codes. Clarified Criteria for Initial Approval. Added exceptions to Dosing table. Updated reference list. Wording and formatting changes.	2/13/2026	2/22/2026
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. Coding Reviewed: 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. CMS Coding Update: Removed HCPCS J9258 and J9259.	4/16/2025	5/6/2025
Annual Review	Update existing criteria for use in breast cancer, pancreatic cancer, and small bowel	2/24/2025	3/6/2025

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	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; Background information revised and updated; References updated; Coding Reviewed: Added HCPCS J9258, J9259.		
Focus Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024
Policy Inception	Elevance Health's Medical Policy adoption	N/A	11/30/2023