# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Paclitaxel, Protein Bound (Abraxane®)** | MP-RX-FP-69-23 | ☒ MMM MA ☒ MMM Multihealth |

Service Category

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

## Service Description

This document addresses the use of Paclitaxel Albumin/Protein Bound (Abraxane®), a taxane primarily used to treat 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
- 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

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- 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. It also has the fallowing 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).

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.
  - 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.

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**Approved Indications**

Paclitaxel Albumin/Protein Bound is a approved by the FDA for the treatment of:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. In this case scenario, prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

**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.

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## Applicable Codes

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 |
| 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 |

## 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.

*Paclitaxel, 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. **Relapsed or metastatic breast cancer** when the following criteria are met (NCCN2A):
   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.

**B. Criteria For Continuation of Therapy**

i. MMM considers continuation of Paclitaxel, 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 an 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: Up to 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):*

1. 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.

## Limits or Restrictions

A. 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. 30 minutes every 3 weeks | Until disease progression or unacceptable toxicity. |
| Non-Small Cell Lung Cancer | 100 mg/m2 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/m2 i.v. on days 1, 8, and 15 of each 28-day cycle (in combination with gemcitabine) | Until disease progression or unacceptable toxicity. |
| **Exceptions** | | |
| None | | |

## Reference Information

1. Abu-Khalaf MM, Baumgart MA, Gettinger SN, et al. Phase 1b study of the mammalian target of rapamycin inhibitor sirolimus in combination with nanoparticle albumin-bound paclitaxel in patients with advanced solid tumors. Cancer. 2015; 121(11):1817-1826.
2. Adkins D, Ley J, Michel L, et al. Nab-paclitaxel, cisplatin, and 5-fluorouracil followed by concurrent cisplatin and radiation for head and neck squamous cell carcinoma. Oral Oncol. 2016; 61:1-7.
3. Adkins D, Ley J, Trinkaus K, et al. A phase 2 trial of induction nab-paclitaxel and cetuximab given with cisplatin and 5-fluorouracil followed by concurrent cisplatin and radiation for locally advanced squamous cell carcinoma of the head and neck. Cancer. 2013; 119(4):766-773.
4. Alberts DS, Blessing JA, Landrum LM, et al. Phase II trial of nab-paclitaxel in the treatment of recurrent or persistent advanced cervix cancer: a gynecologic oncology group study. Gynecol Oncol. 2012; 127(3):451-455.
5. Aldrich JD, Raghav KPS, Varadhachary GR, et al. Retrospective analysis of taxane-based therapy in small bowel adenocarcinoma. Oncologist. 2019;24:e384-6.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
7. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
8. Damascelli B, Patelli G, Ticha V, et al. Feasibility and efficacy of percutaneous transcatheter intraarterial chemotherapy with paclitaxel in albumin nanoparticles for advanced squamous-cell carcinoma of the oral cavity, oropharynx, and hypopharynx. J Vasc Interv Radiol. 2007; 18(11):1395-1403.
9. Demeure MJ, Stephan E, Sinari S, et al. Preclinical investigation of nanoparticle albumin-bound paclitaxel as a potential treatment for adrenocortical cancer. Ann Surg. 2012; 255(1):140-146.
10. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

11. Fan Y, Jiang Y, Zhou X, et al. Phase II study of neoadjuvant therapy with nab-paclitaxel and cisplatin followed by surgery in patients with locally advanced esophageal squamous cell carcinoma. Oncotarget. 2016; 7(31):50624-50634.
12. Fortino S, Santoro M, Iuliano E, et.al. Treatment of Kaposi's Sarcoma (KS) with nab-paclitaxel. Ann Oncol 2016:27:suppl_4: iv124.
13. Grilley-Olson JE, Keedy VL, Sandler A, et al. A randomized phase II study of carboplatin with weekly or every-3-week nanoparticle albumin-bound paclitaxel (Abraxane) in patients with extensive-stage small cell lung cancer. Oncologist. 2015; 20(2):105-106.
14. Hirata T, Yonemori K, Ando M, et al. Efficacy of taxane regimens in patients with metastatic angiosarcoma. Eur J Dermatol. 2011; 21(4):539-545.
15. Huang Y, Liang W, Yang Y, et al. Phase I/II dose-finding study of nanoparticle albumin-bound paclitaxel (nab®-paclitaxel) plus cisplatin as treatment for metastatic nasopharyngeal carcinoma. BMC Cancer. 2016; 16:464.
16. Koizumi W, Morita S, Sakata Y. A randomized Phase III trial of weekly or 3-weekly doses of nab-paclitaxel versus weekly doses of Cremophor-based paclitaxel in patients with previously treated advanced gastric cancer (ABSOLUTE Trial). Jpn J Clin Oncol. 2015; 45(3):303-306.
17. Kottschade LA, Suman VJ, Amatruda T 3rd, et al. A phase II trial of nab-paclitaxel (ABI-007) and carboplatin in patients with unresectable stage IV melanoma: a North Central Cancer Treatment Group Study, N057E(1). Cancer. 2011; 117(8):1704-1710.
18. Ko YJ, Canil CM, Mukherjee SD, et al. Nanoparticle albumin-bound paclitaxel for second-line treatment of metastatic urothelial carcinoma: a single group, multicentre, phase 2 study. Lancet Oncol. 2013; 14(8):769-776.
19. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
20. Li Y, Zeng J, Huang M, et al. A phase 2 study of nanoparticle albumin-bound paclitaxel plus nedaplatin for patients with advanced, recurrent, or metastatic cervical carcinoma. Cancer. 2017; 123(3):420-425.
21. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 29, 2022.
    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.

22. Overman MJ, Adam L, Raghav K, et al. Phase II study of nab-paclitaxel in refractory small bowel adenocarcinoma and CpG island methylator phenotype (CIMP)-high colorectal cancer. Ann Oncol. 2018;29:139-44.
23. 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(12):1707-1712. doi:10.1001/jamaoncol.2018.3277. Available at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2698042. Accessed December 29, 2022.
24. Shepard DR, Dreicer R, Garcia J, et al. Phase II trial of neoadjuvant nab-paclitaxel in high risk patients with prostate cancer undergoing radical prostatectomy. J Urol. 2009; 181(4):1672-1677; discussion 1677.
25. Shi Y, Qin R, Wang ZK, Dai GH. Nanoparticle albumin-bound paclitaxel combined with cisplatin as the first-line treatment for metastatic esophageal squamous cell carcinoma. Onco Targets Ther. 2013; 6:585-591.
26. Tecentriq® (atezolizumab) [Product Information]. San Francisco: Genentech, Inc. Accessed on December 29, 2022.
27. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019 Jul;20(7):924-937. Epub 2019 May 20.

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.



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |
| Select 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 |

Revised: 11/01/2023