nab-paclitaxel (Abraxane®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/17/2021
Lines of Business: Commercial
Policy type: Prior Authorization

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

Drug Description[1]

Albumin-bound paclitaxel is a microtubule inhibitor that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays or "bundles" of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

FDA Indications[1]

Nab-paclitaxel (Abraxane®) is FDA indicated for the following:

- Treatment of patients with metastatic breast cancer who:
  - Failed combination chemotherapy for metastatic disease **OR**
  - Relapse within 6 months of adjuvant chemotherapy
    - Prior therapy should have included an anthracycline unless clinically contraindicated.
- Treatment of patients with locally advanced or metastatic non-small cell lung cancer
  - Combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Treatment of patients with metastatic pancreatic adenocarcinoma
  - Used in combination with gemcitabine.

NCCN Compendium Supported Indications[2]

- Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer
- Hepatobiliary Cancers
- Kaposi Sarcoma
- Melanoma
- Small bowel adenocarcinoma
- Uterine Neoplasms

Coverage Determinations[1,2]

Nab-paclitaxel (Abraxane®) will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met.

Breast Cancer

- The member has a diagnosis of metastatic (Stage IV) or recurrent breast cancer AND
    - The member has had prior therapy or contraindication with an anthracycline (e.g.doxorubicin, epirubicin) **AND**
- The member has a diagnosis of unresectable locally advanced or metastatic triple negative breast cancer AND all of the following apply:
    - the disease is PD-L1 positive (e.g., PD-L1 expression covering greater than or equal to 1% of the tumor area).
    - nab-paclitaxel (Abraxane®) is given in combination with atezolizumab (Tecentriq®).

Recommended dosage: 260 mg/m^2 administered intravenously over 30 minutes every 3 weeks.

Triple Negative Breast Cancer

- The member has a diagnosis of unresectable locally advanced or metastatic TNBC **AND**
        - The disease is PD-L1 positive per FDA approved test (PD-L1 staining on any intensity in tumor infiltrating cells covering ≥ 1% of tumor area) **AND**
    - Paclitaxel protein-bound is given in combination with atezolizumab
        - Please note, the VENTANA PD-L1 (SP142 assay) is the appropriate PD-L1 test to assess for tumor PD-L1 positivity in tumor infiltrating cells
        - Patients enrolled into Impassion 130 were treatment naïve in metastatic setting
            - Benefit of regimen is unknown in subsequent lines of therapy
    - Oncology Analytics recommends restricting usage of nab-paclitaxel plus atezolizumab to the first line setting of triple negative breast cancer

Recommended dosage: 100 mg/m^2 paclitaxel protein-bound in combination with atezolizumab 840 mg. For each 28-day cycle administer atezolizumab on days 1 and 15 and administer paclitaxel protein-bound on days 1, 8, and 15

Non-small Cell Lung Cancer (NSCLC)

- The member has a diagnosis of locally advanced, recurrent, or metastatic NSCLC ***OR***
- The member has squamous histology where Abraxane (nab-paclitaxel) will be given in combination with pembrolizumab (Keytruda®) and carboplatin as first line therapy ***OR***
- The member will be using nab-paclitaxel (Abraxane®) as monotherapy or in combination with carboplatin **AND**
- One of the following apply:
    - The member will be using for first line therapy ***OR***
    - The member will be using as subsequent therapy for EGFR mutation-positive tumors after prior therapy with erlotinib, afatinib, or gefitinib ***OR***
    - The member will be using as subsequent therapy for ALK-positive tumors after prior therapy with crizotinib or ceritinib or alectinib or brigatinib ***OR***
    - The member will be using as subsequent therapy for ROS-1 positive disease after prior therapy with crizotinib ***OR***
    - The member will be using as subsequent therapy for BRAF V600E positive disease ***OR***
    - The member will be using as subsequent therapy after pembrolizumab and EGFR, ALK,BRAF V600E, and ROS-1 negative disease
- Oncology Analytics does not recommend nab-paclitaxel in metastatic non-small cell lung cancer based upon no demonstration of superiority in trials comparing nab-paclitaxel to paclitaxel directly or as part of a treatment regimen

Recommended dosage: 100 mg/m^2 administered intravenously over 30 minutes on days 1,8, and 15 of each 21-day cycle.

Pancreatic Cancer

- The member has a diagnosis of metastatic, unresectable or borderline resectable pancreatic cancer **AND**
    - Abraxane is being used in combination with gemcitabine as neoadjuvant therapy

Recommended dosage: 125 mg/m^2 administered intravenously over 30 minutes on days 1, 8, and 15 of each 28 days cycle.

Hepatobiliary Cancers

- The member has a diagnosis of unresectable or metastatic gallbladder cancer **AND**
    - nab-paclitaxel (Abraxane®) is given in combination with gemcitabine as first-line therapy **OR**
    - nab-paclitaxel (Abraxane®) is given in combination with gemcitabine as subsequent therapy for progression on or after systemic treatment
- The member has a diagnosis of unresectable or metastatic cholangiocarcinoma **AND**
    - nab-paclitaxel (Abraxane®) is given in combination with gemcitabine as first-line therapy **OR**
    - nab-paclitaxel (Abraxane®) is given in combination with gemcitabine as subsequent therapy for progression on or after systemic treatment

Recommended dosage: 125 mg/m^2 administered intravenously over 30 minutes on days 1, 8, and 15 of each 28 days cycle.

Kaposi Sarcoma

- Subsequent systemic therapy, given alone (no HIV) or with antiretroviral therapy (ART) for people with HIV (PWH), for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease that has progressed on or not responded to first-line systemic therapy, and progressed on alternate first-line systemic therapy

Recommended dosage: 100 mg/m^2 administered intravenously over 30 minutes on days 1,8, and 15 of each 21-day cycle.

Melanoma

- The member has a diagnosis of unresectable or metastatic melanoma (cutaneous or uveal melanoma) **AND**
- The member will be using nab-paclitaxel (Abraxane®) as monotherapy **AND**
- The member will be using nab-paclitaxel (Abraxane®) as second-line or subsequent therapy after progression on BRAF targeted therapy

Recommended dosage: 150 mg/m^2 IV over 30 minutes on days 1,8, 15 every 28 days

Ovarian Cancer

- The member has a diagnosis of epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer **AND**
- The member meets one of the following criteria:
    - Progressive, stable or persistent disease on primary chemotherapy ***OR***
    - Recurrent disease

Recommended dosage: 100 mg/m^2 IV over 30 minutes on days 1, 8, 15 on a 28-day schedule.

Small Bowel Adenocarcinoma

- The member has a diagnosis of small bowel adenocarcinoma **AND**
- The member will be using nab-paclitaxel (Abraxane®) as monotherapy or in combination with gemcitabine for advanced metastatic disease categorized as microsatellite stable or proficient mismatch repair with prior oxaliplatin exposure in the adjuvant setting or contraindication ***OR***
- The member will be using nab-paclitaxel (Abraxane®) for subsequent therapy as monotherapy or in combination with gemcitabine for advanced disease that is:
    - microsatellite stable of proficient mismatch repair (MSS or pMMR) in members who are appropriate for intensive therapy
    - deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) only in members who progressed through pembrolizumab (Keytruda®) or nivolumab (Opdivo®) with or without ipilimumab (Yervoy®)
    - MSS or pMMR in members who are not appropriate for intensive therapy and progressed through FOLFOX or irinotecan

- dMMR/MSI-H only in members with prior oxaliplatin exposure in the adjuvant setting or contraindication and progressed through pembrolizumab (Keytruda®) or nivolumab (Opdivo®) with or without ipilimumab (Yervoy®).

Recommended dosage: 220 mg/m^2 IV over 30 minutes every 21 days.

Uterine Neoplasms

- Primary treatment as a single agent in Endometrioid adenocarcinoma:
  - may be considered preoperatively for patients presenting with abdominal/pelvic confined disease that is suitable for primary surgery
  - with sequential EBRT and with or without brachytherapy for locoregional extrauterine disease that is not suitable for primary surgery
  - with or without EBRT and/or stereotactic body radiation therapy for distant metastases that are suitable for primary surgery
  - for distant metastases that are not suitable for primary surgery
- Adjuvant treatment for surgically staged patients as a single agent in Endometrioid adenocarcinoma:
  - with or without EBRT and with or without vaginal brachytherapy for stage III-IV disease
- Single-agent therapy in Carcinosarcoma, Clear Cell Carcinoma, Endometrioid adenocarcinoma, Serous Carcinoma, Undifferentiated/dedifferentiated carcinoma:
  - for disseminated metastases
  - with sequential external beam radiation therapy (EBRT) and with or without brachytherapy for locoregional recurrence in patients with no prior RT to site of recurrence, or previous brachytherapy only
  - after surgical exploration, with sequential EBRT for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissue, or in pelvic, para-aortic or common iliac lymph nodes
  - after surgical exploration, with or without sequential EBRT for locoregional recurrence in patients with upper abdominal or peritoneal disease
  - with or without sequential palliative EBRT or brachytherapy for locoregional recurrence in patients who have received prior EBRT to site of recurrence
- Single-agent therapy in Carcinosarcoma, Clear Cell Carcinoma, Serous Carcinoma, Undifferentiated/dedifferentiated carcinoma:
  - for disease that is suitable for primary surgery as additional treatment with vaginal brachytherapy for stage IA disease (preferred)
  - for disease that is suitable for primary surgery as additional treatment with or without sequential external beam radiation therapy (EBRT) and with or without vaginal brachytherapy for stage IB-IV disease
  - for disease that is not suitable for primary surgery as primary treatment with or without sequential EBRT and with or without brachytherapy

Recommended dosage:

- 260 mg/m^2 IV over 30 minutes on Day 1 every 21 days **OR**
- 100 - 125 mg/m^2 administered intravenously over 30 minutes on days 1, 8, and 15 of each 28 days cycle.

All indications:

- Nab-paclitaxel will be approved through clinical review for up to a 6-month duration.

Coverage Limitations

Treatment with nab-paclitaxel is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on nab-paclitaxel.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- Neutrophil counts of <1500 cells/mm^3
- Severe hypersensitivity reaction to nab-paclitaxel.
- Myelosuppression monitor CBC and withhold and/or reduce the dose as needed.
- Sensory neuropathy occurs frequently and may require dose reduction or treatment interruption.
- The most common adverse reactions (≥ 20%) in metastatic breast cancer are alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, infections, and diarrhea.
- The most common adverse reactions (≥ 20%) in NSCLC are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue.
- The most common (≥ 20%) adverse reactions of ABRAXANE in adenocarcinoma of the pancreas are neutropenia, fatigue, peripheral neuropathy, nausea, alopecia, peripheral edema, diarrhea, pyrexia, vomiting, decreased appetite, rash, and dehydration

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- **Description**: inj., nab-paclitaxel, 1 mg
    - HCPCS: J9264

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines

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References

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