nab-paclitaxel (Abraxane®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
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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.

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NCCN Compendium Supported Indications[2]

- Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer
- Melanoma
- Small bowel adenocarcinoma

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

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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 30-40 minutes on days 1, 8, and 15 of each 28 days cycle.

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

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

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 AND

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

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 every 21 days.

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

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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 may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

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2. Paclitaxel, albumin bound. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/

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