Abraxane (nab) paclitaxel

Humana

Pharmacy Coverage Policy

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Abraxane [nano-particle albumin bound (nab) paclitaxel], an antimicrotubule agent, promotes microtubule assembly from tubulin dimers and stabilizes microtubules to prevent depolymerization. This stability causes inhibition of the normal dynamic reorganization of the microtubules which is necessary for important interphase and mitotic functions in the cells.

Abraxane (nab-paclitaxel) is indicated for 1) the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy, prior therapy should have included an anthracycline unless clinically contraindicated; 2) 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; and 3) metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

Nab-paclitaxel is available as Abraxane in a 100 mg vial for injection.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted

indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- **National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium**
- **Truven Health Analytics Micromedex DrugDEX**
- **Elsevier/Gold Standard Clinical Pharmacology**

Wolters Kluwer Lexi-Drugs

Abraxane (nab-paclitaxel) will require prior authorization. This agent may be considered medically necessary when the following criteria 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 documented hypersensitivity reaction to conventional Taxol (paclitaxel) and Taxotere (docetaxel) or the member has a documented contraindication to standard hypersensitivity premedications

Melanoma

- **The member has a diagnosis of unresectable or metastatic melanoma AND**
- **The member will be using Abraxane (nab-paclitaxel) as monotherapy AND**
- **The member will be using Abraxane (nab-paclitaxel) as second-line or subsequent**

therapy after progression on BRAF targeted therapy AND

- **The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) and Taxotere (docetaxel) or the member has a documented contraindication to standard hypersensitivity premedications**

Non-small Cell Lung Cancer (NSCLC)

- **The member has a diagnosis of locally advanced, recurrent, or metastatic NSCLC AND**
- **The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) and Taxotere (docetaxel) or the member has a documented contraindication to standard hypersensitivity premedications. AND**
- **The member has squamous histology where Abraxane (nab-paclitaxel) will be given in combination with Keytruda (pembrolizumab) and carboplatin as first line therapy**

OR

- **The member will be using Abraxane (nab, paclitaxel) 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 OR**
  - **The member will be using as subsequent therapy for ALK-positive tumors after prior therapy OR**
  - **The member will be using as subsequent therapy for ROS-1 positive disease after prior therapy 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 OR

- **The member has metastatic NSCLC, non- squamous histology with no EGFR or ALK**

genomic tumor aberrations AND

- **Abraxane (nabpaclitaxel) will be given combination with Tecentriq (atezolizumab) and carboplatin as first line therapy**

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**

AND

- **The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) and Taxotere (docetaxel) or the member has a documented contraindication to standard hypersensitivity premedication**

Pancreatic Cancer

The member has a diagnosis of pancreatic cancer AND

- **Abraxane is being used in combination with gemcitabine as neoadjuvant therapy**

OR

- **The member has a diagnosis of metastatic pancreatic cancer AND**
  - **The member will be using Abraxane (nab-paclitaxel) in combination with gemcitabine**

Abraxane (nab-paclitaxel) will be approved in six month durations or as determined through clinical review.

Coverage Limitations

Abraxane (nab-paclitaxel) therapy is not considered medically necessary for members with the following concomitant conditions:

- **Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.**

Background

This is a prior authorization policy about Abraxane (nab-paclitaxel).

Black Box Warning:

Abraxane (nab-paclitaxel) therapy should not be administered to patients who have baseline neutrophil counts of less than 1,500 cells/mm^3. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Abraxane (nab-paclitaxel).

Note: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS.

Dosage Adjustments:

Please note that dose adjustments vary by indication. Please see Full Prescribing Information for complete recommendations regarding dose adjustments.

Abraxane (nab-paclitaxel) should not be utilized in the following:

- **Baseline neutrophil counts of less than 1500 cells/cubic millimeter**

- **Use in pediatric members <18 years old**
- **Use in members that are pregnant or breast feeding and have not been apprised of risk**
- **Members who experience severe hypersensitivity adverse effect should not be rechallenged with Abraxane (nab-paclitaxel)**
- **See also Coverage Limitations section of this policy.**

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Abraxane; nab-paclitaxel; nano-particle albumin bound paclitaxel; breast cancer; lung cancer; ovarian cancer; intravenous; pharmacy

References

Abraxane [prescribing information]. Celgene Corporation. Summit, NJ. July 2015.
National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. updated periodically.

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