09-J1000-05

Original Effective Date: 05/15/09

Reviewed: 03/12/25

Revised: 04/15/25

Subject: Nab-Paclitaxel Injection (Abraxane®)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Nano-particle albumin-bound (Nab)-Paclitaxel (Abraxane®) is formulated using nanotechnology to combine human albumin to paclitaxel. Paclitaxel is the active component of the formulation and is an antimicrotubule agent 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. It induces abnormal arrays or “bundles” of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis. Tumor penetration is facilitated by albumin-receptor mediated endothelial transcytosis. Because nab-paclitaxel does not contain solvents, there is a reduced risk of certain hypersensitivity-related side effects. As such, hypersensitivity premedications, such as steroids and antihistamines, are not necessary.

Current National Comprehensive Cancer Network (NCCN) guidelines support the use of nab-paclitaxel in AIDs-related Kaposi Sarcoma, ampullary adenocarcinoma, breast cancer, cholangiocarcinoma, endometrial cancer, gallbladder cancer, melanoma, non-small cell lung cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer, small bowel adenocarcinoma, pancreatic cancer, uveal cancer, and vaginal cancer..

POSITION STATEMENT:

Initiation of nab-paclitaxel (Abraxane) IV **meets the definition of medical necessity** when administered for the indications listed in Table 1 and **ALL** of the indication-specific criteria are met:

Table 1

Indication	Specific Criteria
Ampullary Adenocarcinoma	When **ALL** of the following are met: 1. Member has pancreatobiliary or mixed type disease 2. Nab-paclitaxel is used in combination with gemcitabine 3. The dose does not exceed 375 mg/m^2 every 28 days
Breast Cancer	When **ALL** of the following are met: 1. **ONE** of the following is met: A. Nab-paclitaxel will be used in combination with pembrolizumab for triple-negative breast cancer for **ONE** of the following: i. PD-L1 positive disease and ONE of the following: 1. Recurrent, unresectable disease 2. Metastatic disease 3. Disease that is unresponsive to preoperative systemic therapy ii. High-risk early-stage disease when used in combination with carboplatin B. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) and nab-paclitaxel will be used as a single agent or with **ONE** of the following: i. capecitabine ii. carboplatin iii. carboplatin/trastuzumab iv. carboplatin/trastuzumab/pertuzumab v. cyclophosphamide vi. cyclophosphamide/trastuzumab vii. doxorubicin/cyclophosphamide viii. gemcitabine ix. trastuzumab x. trastuzumab/pertuzumab

	2. The dose does not exceed **ONE** of the following: A. 450 mg/m^2 every 28 days B. 260 mg/m^2 every 21 days C. 125 mg/m^2 every 7 days
Cervical cancer	When **ALL** of the following are met: 1. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) 2. Nab-paclitaxel is used as second-line or subsequent therapy 3. Nab-paclitaxel is used as a single agent 4. The dose does not exceed 375 mg/m^2 every 28 days
Cholangiocarcinoma (bile duct cancer)	When **ALL** of the following are met: 1. Member has unresectable, metastatic disease, or resected gross residual (R2) disease 2. Nab-paclitaxel is used in combination with gemcitabine (Gemzar) 3. The dose does not exceed 375 mg/m^2 every 28 days
Endometrial carcinoma	When **ALL** of the following are met: 1. Nab-paclitaxel will be given as a single agent or in combination with **ONE** of the following: i. carboplatin (with or without bevacizumab) ii. carboplatin and dostarlimab-gxly iii. carboplatin and durvalumab iv. carboplatin and pembrolizumab v. carboplatin and trastuzumab vi. cisplatin and doxorubicin vii. ifosfamide 2. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) 3. The dose does not exceed 300 mg/m^2 every 28 days

Gallbladder cancer	When **ALL** of the following are met: 1. Member has unresectable, metastatic, locoregionally advanced disease, or resected gross residual (R2) disease 2. Nab-paclitaxel is used in combination with gemcitabine (Gemzar) 3. The dose does not exceed 375 mg/m^2 every 28 days
Kaposi Sarcoma	When **ALL** of the following are met: 1. Member has relapsed or refractory disease 2. Member had disease progression on or after second-line systemic chemotherapy 3. Nab-paclitaxel is used as a single agent 4. The dose does not exceed 300 mg every 28 days
Melanoma	When **ALL** of the following are met: 1. Nab-paclitaxel is used as a single agent or in combination with carboplatin 2. Member's disease is metastatic or unresectable 3. Nab-paclitaxel is used as second-line or subsequent therapy 4. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) 5. The dose does not exceed 450 mg/m^2 every 28 days
Non-small cell lung cancer (NSCLC)	When **ALL** of the following are met: 1. Nab-paclitaxel is used as a single agent or in combination with **ONE** of the following: a. carboplatin (with or without bevacizumab) b. carboplatin and atezolizumab c. carboplatin, durvalumab, and tremelimumab-actl d. carboplatin and cemiplimab-rwlc e. carboplatin and pembrolizumab f. carboplatin, nivolumab and ipilimumab g. cisplatin h. cisplatin and cemiplimab-rwlc i. gemcitabine

	2. Member's disease is advanced, recurrent, or metastatic 3. The dose does not exceed 300 mg/m^2 every 21 days
Ovarian cancer [including epithelial ovarian cancer, fallopian tube cancer, primary peritoneal carcinoma, and less common ovarian histologies (carcinosarcoma, clear cell carcinoma, mucinous carcinoma, low-grade serous/grade1 endometrioid, malignant sex germ cell tumors, malignant sex cord-stromal tumors)]	When **ALL** of the following are met: 1. When **ONE** of the following is met a. Nab-paclitaxel is used as a single agent b. Nab-paclitaxel is used in combination with carboplatin 2. Member's disease is recurrent or persistent 3. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) 4. The dose does not exceed 260 mg/m^2 every 21 days
Pancreatic cancer	When **ALL** of the following are met: 1. Member's meets **ONE** of the following: a. When used for **ONE** of the following: i. Metastatic disease ii. Locally advanced disease iii. Recurrent disease b. Nab-paclitaxel will be used as neoadjuvant treatment for **ONE** of the following: i. Borderline resectable disease ii. Resectable disease 2. **ONE** of the following: a. Nab-paclitaxel is used in combination with gemcitabine (Gemzar) b. Nab-paclitaxel is used in combination with gemcitabine and cisplatin 3. The dose does not exceed 375 mg/m^2 every 28 days
Small Bowel Adenocarcinoma	When **ALL** of the following are met: 1. When **ONE** of the following is met a. Nab-paclitaxel is used as a single agent

	b. Nab-paclitaxel is used in combination with gemcitabine 2. Member's disease is advanced or metastatic 3. Member has a documented hypersensitivity to conventional paclitaxel (Taxol), docetaxel (Taxotere), or to standard hypersensitivity premedications (e.g., diphenhydramine, H2 receptor antagonists, corticosteroids) 4. The dose does not exceed 375 mg/m^2 every 28 days
Uveal melanoma	When **ALL** of the following are met: 1. Nab-paclitaxel is used as a single agent 2. Member's disease is metastatic or unresectable 3. The dose does not exceed 450 mg/m^2 every 28 days
Vaginal cancer	When **ALL** of the following are met: 1. Nab-paclitaxel is used as a single agent 2. Member's disease is metastatic or recurrent 3. Nab-paclitaxel is used as second-line or subsequent therapy 4. The dose does not exceed 375 mg/m^2 every 28 days

Duration of approval: 6 months

Continuation of nab-paclitaxel (Abraxane) **meets the definition of medical necessity** for the indications in Table 1 when the following criteria are met:

1. The member has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member has previously met all indication-specific criteria for coverage
2. Member's disease has not progressed while receiving nab-paclitaxel
3. The dose does not exceed indication-specific dosing found in Table 1

Duration of approval: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING IT'S USAGE.

Nab-Paclitaxel dosage is based on the treated indication. See prescribing information for dose reduction for hepatic impairment and adverse events. Do not substitute for or with other paclitaxel formulations and closely monitor the infusion site for extravasation and infiltration.

- Metastatic breast cancer (MBC): 260mg/m^2 IV every 21 days

- Non-small cell lung cancer (NSCLC) or ovarian cancer: 100mg/m^2 IV on days 1, 8, and 15 every 28 days. Administer carboplatin on Day 1 of each cycle immediately after nab-paclitaxel.
- Adenocarcinoma of the pancreas: 125 mg/m^2 on days 1, 8, and 15 every 28 days. Administer gemcitabine on Days 1, 8, and 15 of each 28-day cycle immediately after nab-paclitaxel.

Dose adjustment:

- Use not recommended for patients with AST > 10 x upper limit of normal (ULN) or bilirubin >5 x ULN or with metastatic adenocarcinoma of the pancreas who have moderate to severe hepatic impairment.
- For MBC or NSCLC indications, reduce the starting dose for moderate to severe hepatic impairment.

Drug Availability

Nab-paclitaxel: supplied as a 100 mg vial (powder for injection)

PRECAUTIONS:

Boxed Warning

- Do not administer to individuals with a baseline neutrophil count of less than 1500 cells/mm^3
- Monitor for neutropenia, which may be severe and result in infection or sepsis
- Complete blood cell counts should be monitored frequently to assess for occurrence of bone marrow suppression.

Contraindications

- Neutrophil count less than 1500 cells/mm^3
- Severe hypersensitivity to nab-paclitaxel (members should not be re-challenged if they experience hypersensitivity).

Warnings and Precautions

- Hypersensitivity: severe and fatal reactions have occurred. Do not re-challenge with this drug.
- Myelosuppression: monitor complete blood count and withhold and/or reduce the dose as needed.
- Neuropathy: sensory neuropathy occurs frequently and may require reduction or treatment interruption.
- Hepatic impairment: administer with caution in persons with hepatic impairment as exposure and toxicity of paclitaxel can be increased in this population.
- Fetal harm: women should avoid becoming pregnant; men should avoid fathering a child.
- Sepsis: this occurred in patients with or without neutropenia when used in combination with gemcitabine. Interrupt therapy if sepsis occurs.

- Pneumonitis: this occurred when used in combination with gemcitabine. Permanently discontinue.
- Viral transmission: Albumin is derived from human blood and a theoretical risk of viral transmission exists.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding:

J9264	Injection, paclitaxel protein-bound particles, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity for Nab-Paclitaxel (protein-bound, Abraxane®) (J9264):

C17.0 – C17.9	Malignant neoplasm of small intestine
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7 – C25.8	Malignant neoplasm of other parts or overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
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
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
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 corpus uteri
C55	Malignant neoplasm of uterus, part unspecified
C56.1 – C57.9	Malignant neoplasm of ovary, fallopian tube, broad ligament, round ligament, parametrium and uterine adnexa, unspecified
C69.30 – C69.32	Malignant neoplasm of choroid
C69.40 – C69.42	Malignant neoplasm of ciliary body
C69.60 – C69.62	Malignant neoplasm of orbit

C79.31	Secondary malignant neoplasm of brain
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Bevacizumab (Avastin®) Injection, 09-J0000-66

Doxorubicin HCl Liposome (Doxil®) IV, 09-J0000-91

Trastuzumab (Herceptin®) Injection, 09-J0000-86

OTHER:

ECOG Performance Status	
Grade	**ECOG**
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, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/12/25.

GUIDELINE UPDATE INFORMATION:

05/15/09	New Medical Coverage Guideline.
10/15/09	Revision; consisting of clarifying maximum dosage and updating coding.
01/15/10	Revision; consisting of updating coding.

04/15/10	Revision; consisting of updating coding.
07/15/10	Review and revision; consisting of updating references.
08/01/10	Revision; consisting of updating coding.
02/01/11	Revision; consisting of adding new indication and updating coding.
07/15/11	Review and revision to guideline; consisting of updating coding and references.
08/15/11	Revision to guideline; consisting of updating coding.
10/01/11	Revision to guideline; consisting of updating coding.
07/15/12	Review and revision to guideline; consisting of updating position statement, coding exceptions and references.
10/15/12	Revision to guideline; consisting of removing non-melanoma skin cancer indication and updating coding.
02/15/13	Revision to guideline; consisting of updating coding.
07/15/13	Review and revision to guideline; consisting of revising position statement to include NCCN compendia category 1 and 2A recommendations, orphan drug designations, and approval durations; revised dosage/administration and precautions; updating coding, program exceptions and references.
10/15/13	Revision to guideline; consisting of adding advanced or metastatic melanoma as medically necessary and updating coding.
07/15/14	Review and revision to guideline; consisting of updating references, revising and reformatting position statement
01/01/15	Revision to guideline; consisting of annual HCPCS coding update
07/15/15	Review and revision to guideline; consisting of revising position statement to include NCCN compendia category 1 and 2A recommendations; revised dosage/administration and precautions; updating coding, and references.
09/15/15	Revision to guideline; consisting of updating coding and docetaxel hypersensitivity.
10/01/15	Revision consisting of update to Program Exceptions section.
11/01/15	Revision: ICD-9 Codes deleted.
01/15/16	Revision to guideline; consisting of updating position statement and references.
07/15/16	Review and revision to guideline; consisting of updating position statement, coding and references.
10/01/16	Update to ICD-10 codes.
11/15/16	Revision to guideline; consisting of updating position statement, coding, and references.
01/15/17	Revision to guideline; consisting of updating position statement and references.
07/15/17	Review and revision to guideline; consisting of updating position statement, description, dosing, coding and references.
04/15/18	Review and revision to guideline; consisting of updating position statement, coding and references.
07/15/18	Review and revision to guideline; consisting of updating position statement, coding and references.
08/15/18	Revision to guideline; consisting of updating position statement and references.
05/15/19	Revision to guideline; consisting of updating position statement, coding and references.
06/15/19	Revision to guideline; consisting of updating position statement and references.
08/15/19	Review and revision to guideline; consisting of updating references.

05/15/20	Revision to guideline; consisting of updating position statement and references.
08/15/20	Review and revision to guideline; consisting of updating position statement. description, coding and references.
04/15/21	Revision to guideline; consisting of updating the position statement and references.
07/15/21	Review and revision to guideline; consisting of updating position statement. dosing, warnings, coding, and references.
08/15/22	Review and revision to guideline; consisting of updating position statement, coding, and references.
07/01/23	Revision: Added HCPCS code J9259.
08/15/23	Review and revision to guideline; consisting of updating position statement to include cervical cancer and updates to breast cancer, bile duct cancer, endometrial cancer, gallbladder cancer, non-small cell lung cancer, and pancreatic cancer indications. Update to coding and references.
01/01/24	Revision: Added HCPCS code J9258.
02/15/24	Review and revision to guideline; consisting of updating the position statement for breast cancer, non-small cell lung cancer, and pancreatic cancer (NCCN).
07/01/24	Revision: Revision to HCPCS codes J9258 and J9259.
10/01/24	Revision: Removed HCPCS code J9258. Per CMS, Teva's paclitaxel product is now considered as a multisource drug to be billed under Abraxane's existing HCPCS code J9264.
01/01/25	Revision: Removed HCPCS code J9259.
04/15/25	Review and revision to guideline; consisting of updating the position statement for gallbladder cancer and endometrial cancer and adding vaginal cancer.