BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Paclitaxel (Abraxane®)

File Name:	paclitaxel_abraxane
Origination:	8/2016
Last CAP Review:	4/2020
Next CAP Review:	4/2021
Last Review:	4/2020

Description of Procedure or Service

Paclitaxel (Abraxane) is a microtubule inhibitor indicated for the treatment of metastatic breast cancer, locally advanced or metastatic non-small cell lung cancer (NSCLC), and metastatic adenocarcinoma of the pancreas.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Paclitaxel (Abraxane) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Paclitaxel (Abraxane®) is covered

Paclitaxel (Abraxane®) is considered medically necessary for the treatment of patients with:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
- 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.

Use of Paclitaxel (Abraxane) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**

- In accordance with specific strong endorsement or support by nationally recognized

compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Paclitaxel (Abraxane®) is not covered

Paclitaxel (Abraxane) is considered not medically necessary and therefore not covered when above criteria are not met.

Paclitaxel (Abraxane) is considered investigational when used for:

1. Non-cancer indications; **OR**

2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Paclitaxel (Abraxane) is covered."

Policy Guidelines

Dosage and Administration:

- Metastatic Breast Cancer: Recommended dosage of Abraxane is 260 mg/m^2 intravenously over 30 minutes every 3 weeks; or 100 to 150 mg/m^2 intravenously on days 1, 8, and 15.
- Non-Small Cell Lung Cancer: Recommended dosage of Abraxane is 100 mg/m^2 intravenously over 30 minutes on Days 1, 8, and 15 of each 21-day cycle; administer carboplatin on Day 1 of each 21-day cycle immediately after Abraxane.
- Adenocarcinoma of the Pancreas: Recommended dosage of Abraxane is 125 mg/m^2 intravenously over 30-40 minutes on Days 1, 8 and 15 of each 28-day cycle; administer gemcitabine on Days 1, 8 and 15 of each 28-day cycle immediately after Abraxane.

Limitations of Use:
Do not administer Abraxane therapy to patients with baseline neutrophil counts of less than 1,500 cells/mm^3.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *J9264, S0353, S0354*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021660s040lbl.pdf

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;14:769-76. PMID:23706985

Medical Director review 3/2017

Specialty Matched Consultant Advisory Panel 4/2017

Specialty Matched Consultant Advisory Panel 4/2018

Medical Director review 6/2018

Specialty Matched Consultant Advisory Panel 4/2019

Specialty Matched Consultant Advisory Panel 4/2020

Policy Implementation/Update Information

12/30/16 New policy issued. Paclitaxel (Abraxane®) is considered medically necessary for the treatment of patients with: Metastatic breast cancer, locally advanced or metastatic non-small cell lung cancer (NSCLC), metastatic adenocarcinoma of the pancreas. Removed statement "prior therapy should have included an anthracycline unless clinically contraindicated" in the "When Covered" section. Medical Director review 9/2016. Added HCPCS codes S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. (lpr)

5/26/17 Added the following statement to "When Covered" section: "Use of Paclitaxel (Abraxane) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); OR In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached". Under "When Not Covered" section, added the statement "Paclitaxel (Abraxane) is considered investigational when used for: 1)Non-cancer indications; **OR** 2) When criteria are not met regarding FDA labeling **OR** strong endorsement/ support by nationally recognized compendia, as stated under "When Paclitaxel (Abraxane) is covered." Added the following statements under "Policy Guidelines" section: 1)Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services." 2) Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia. Medical director review 3/2017. Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)

6/29/18 Specialty Matched Consultant Advisory Panel review 4/25/2018. Added additional weekly dosing parameters for metastatic breast cancer to "Policy Guidelines" section. No change to policy intent. Medical Director review 6/2018. (krc)

4/30/19 Specialty Matched Consultant Advisory Panel review 4/17/2019. No change to policy statement. (krc)

6/9/20 Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statement. (krc)