Blue Cross Blue Shield Blue Care Network of Michigan

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P&T Date: 02/13/2025

Nab-Paclitaxel; Paclitaxel Protein-Bound Particles

HCPCS: J9264

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. Metastatic breast cancer
      i. After failure of combination therapy
         a) Combination should have included anthracycline unless contraindicated
      ii. Relapse within 6 months of adjuvant therapy
      iii. To be used as monotherapy
      iv. Should not be used if previous treatment failure with Abraxane
      v. Trial and failure, contraindication, or intolerance to generic paclitaxel
   b. Non-small cell lung cancer
      i. First line therapy
      ii. In combination with carboplatin
      iii. For patients who are not candidates for surgical resection with locally advanced or metastatic disease
      iv. Trial and failure, contraindication, or intolerance to generic paclitaxel
   c. Adenocarcinoma of the pancreas
      i. In combination with gemcitabine only

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Treatment continued until unacceptable toxicity or disease progression

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Paclitaxel protein bound is indicated for use in metastatic breast cancer, non-small cell lung cancer (NSCLC), and metastatic adenocarcinoma of the pancreas.

- When given to treat metastatic breast cancer, paclitaxel protein-bound is FDA approved as monotherapy following treatment failure with combination therapy containing an anthracycline unless it is contraindicated or if the patient has relapsed within 6 months of adjuvant therapy. The National Comprehensive Cancer Network (NCCN) 2023 treatment guidelines for breast cancer do not recommend use of paclitaxel protein-bound following previous treatment failure with it.

- When used in NSCLC, paclitaxel protein-bound is FDA approved as first-line therapy in combination with carboplatin in patients with locally advanced or metastatic disease that is not surgically resectable.

- The indication for pancreatic cancer required the drug be used as first-line therapy and in combination with gemcitabine.

- In situations where paclitaxel is indicated but hypersensitivity has contraindicated continued use, the 2023 NCCN guidelines for breast cancer and NSCLC state paclitaxel protein-bound can be substituted for paclitaxel.

- Treatment with paclitaxel protein-bound should continue until disease progression or unacceptable toxicity.

References:

1. Abraxane [prescribing information]. Summit, NJ: Celgene Corporation; December 2022.
2. National Comprehensive Cancer Network. Breast cancer (Version 6.2024). 2024 Nov 11. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on December 10, 2024.
3. National Comprehensive Cancer Network. Non-small cell lung cancer (Version 11.2024). 2024 Oct 15. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 10, 2024.
4. National Comprehensive Cancer Network. Pancreatic adenocarcinoma (Version 3.2024). 2024 August 2. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed on December 10, 2024.
5. Gradishar WJ, Tjulandin S, Davidson N, et al. Phase III trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol. 2005; 23 (31): 7794 - 803.
6. Damascelli B, Cantu G, Mattavelli F, et al. Intraarterial chemotherapy with polyoxyethylated castor oil free paclitaxel, incorporated in albumin nanoparticles (ABI 007): phase I study of patients with squamous cell carcinoma of the head and neck and anal canal: preliminary evidence of clinical activity. Cancer. 2001; 92: 2592 - 602.
7. Socinski MA, Bondarenko I, Karaseva NA, et al. Weekly nab-paclitaxel in combination with carboplatin versus solvent-based paclitaxel plus carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer. J Clin Oncol. 2012 Jun 10; 30 (17): 2055 - 62.
8. VonHoff DD, Ervin T, Arena FP, et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. New Eng J Med. 2013; 369 (18): 1691 - 703.
9. Paclitaxel Protein-Bound Particles [prescribing information]. Brea, CA: HBT Labs, Inc.; July, 2022.

Policy History		
#	Date	Change Description
2.7	Effective Date: 02/13/2025	Annual review of policy - no changes were made to the criteria
2.6	Effective Date: 01/01/2025	Removal of J9258 and J9259 due to CMS discontinuation
2.5	Effective Date: 02/08/2024	Updated to list trial and failure of generic paclitaxel for the metastatic breast cancer and non-small cell lung cancer indications and remove the bullet requiring the step for pancreatic cancer as that is not guideline supported. The title of the policy was changed from Abraxane to Nab-paclitaxel; Paclitaxel Protein-Bound Particles.
2.4	Effective Date: 01/01/2024	UM medical management system update to BCBS, BCN, MAPPO, and BCNA for J-code 9258
2.3	Effective Date: 02/02/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days
2.2	Effective Date: 10/06/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time
2.1	Effective Date: 10/07/2021	Annual review of policy. No changes were made to the criteria
2.0	Effective Date: 12/01/2020	UM medical management system update to BCBS for Abraxane
1.9	Effective Date: 10/08/2020	Updated approval duration to 6 months at a time and updated renewal criteria to allow use until unacceptable toxicity or disease progression
1.8	Effective Date: 01/01/2020	UM medical management system update to MAPPO and BCNA for Abraxane
1.7	Effective Date: 11/07/2019	Annual Review of Medical Policy
1.6	Effective Date: 08/01/2019	UM medical management system update to BCN for Abraxane
1.5	Effective Date: 11/01/2018	Updated criteria per oncology vendor
1.4	Effective Date: 08/09/2018	Annual Review of Medical Policy
1.3	Effective Date: 08/10/2017	Annual Review of Medical Policy
1.2	Effective Date: 08/11/2016	Annual Review of Medical Policy
1.1	Effective Date: 12/16/2013	Update for new indication
1.0	Effective Date: 12/17/2012	New Criteria

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*