



Paclitaxel Protein Bound Particles (Abraxane®)
Revision: 3

Policy Number: M-0015
Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA:

- Breast cancer, following failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant therapy

Off Label:

- Anal cancer
- Head and neck cancer
- Metastatic breast cancer, First-line treatment as monotherapy
- Non-small cell lung cancer, Advanced or metastatic, first-line treatment, in combination with carboplatin and bevacizumab



Coding Information:

HCPCS Code(s)

J9264	INJECTION, PACLITAXEL PROTEIN-BOUND PARTICLES, 1 MG
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ICD-9 Code(s)

157.0-157.9	MALIGNANT NEOPLASM OF HEAD OF PANCREAS - MALIGNANT NEOPLASM OF PANCREAS PART UNSPECIFIED when used in combination with Gemcitabine
158.8-158.9	MALIGNANT NEOPLASM OF SPECIFIED PARTS OF PERITONEUM - MALIGNANT NEOPLASM OF PERITONEUM UNSPECIFIED
162.0	MALIGNANT NEOPLASM OF TRACHEA
162.2-162.5	MALIGNANT NEOPLASM OF MAIN BRONCHUS - MALIGNANT NEOPLASM OF LOWER LOBE BRONCHUS OR LUNG
162.8-162.9	MALIGNANT NEOPLASM OF OTHER PARTS OF BRONCHUS OR LUNG - MALIGNANT NEOPLASM OF BRONCHUS AND LUNG UNSPECIFIED
174.0-174.9	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
175.0-175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
183.0	MALIGNANT NEOPLASM OF OVARY
183.2-183.5	MALIGNANT NEOPLASM OF FALLOPIAN TUBE - MALIGNANT NEOPLASM OF ROUND LIGAMENT OF UTERUS
183.8-183.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA - MALIGNANT NEOPLASM OF UTERINE ADNEXA UNSPECIFIED SITE
V10.43	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF OVARY

Background:

Abraxane is in a class of medications called antimicrotubule agents. It works by stopping the growth and spread of cancer cells. Abraxane 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.



Black Box Warning:

WARNING: NEUTROPENIA

- **ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than 1,500 cells/mm³. 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.**
- **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.**

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

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2. NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma. Available at: http://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed August 1, 2013.
3. Local Coverage Article for Drugs and Biologicals – Chemotherapeutic Agents (A48896) (R4). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=89&ContrlId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2013&DocID=A48896&bc=hAAAAAgAEAAAAA%3d%3d&. Accessed June 4, 2014.



4. Micromedex® 2.0 Abraxane. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/AD7DC5/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/C378B8/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=928375&contentSetId=100&title=Paclitaxel+Protein-Bound&servicesTitle=Paclitaxel+Protein-Bound&topicId=dosingAndIndicationsSection&subtopicId=nonfdaSection. Accessed 6-6-12
5. Löhr JM, Haas SL, Bechstein WO, et al. Cationic liposomal paclitaxel plus gemcitabine or gemcitabine alone in patients with advanced pancreatic cancer: a randomized controlled phase II trial. *Ann Oncol.* 2012 May;23(5):1214-22.

Document History:

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