


Abraxane[®]
for Injectable Suspension
(paclitaxel protein-bound particles for injectable suspension)
(albumin-bound)

 **Bristol Myers Squibb[®]**
Access Support[®] >

A REFERENCE GUIDE TO
**Reimbursement and
Coding ABRAXANE[®] for
Injectable Suspension**
(paclitaxel protein-bound particles
for injectable suspension)
(albumin-bound)



Please see [Important Safety Information](#) on pages 24-29
and [U.S. Full Prescribing Information](#), including **Boxed WARNING**.

Indications

ABRAXANE® is indicated for 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.

ABRAXANE® is indicated for the first-line treatment of locally advanced or metastatic non–small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

ABRAXANE® is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

Select Important Safety Information: **Boxed WARNING**

WARNING: SEVERE MYELOSUPPRESSION

- Do not administer ABRAXANE therapy to patients with baseline neutrophil counts of less than 1500 cells/mm³.
- Monitor for neutropenia, which may be severe and result in infection or sepsis. Perform frequent complete blood cell counts on all patients receiving ABRAXANE.

Please see [Important Safety Information](#) on pages 24–29 and [U.S. Full Prescribing Information](#), including **Boxed WARNING**.

For reimbursement assistance, call BMS Access Support® at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday,

or visit www.BMSAccessSupport.com.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to BMS medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that healthcare provider offices verify each patient's insurance coverage prior to initiating therapy.

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Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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National Drug Code (NDC) Information and Storage for ABRAXANE[®] for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

The NDCs for ABRAXANE, listed below, are often necessary in addition to the appropriate J code when filing a claim for reimbursement.

NDCs for ABRAXANE¹

ABRAXANE injection 100 mg/vial

100 mg of paclitaxel in a single-dose vial, individually packaged in a carton

68817-134-50

68817-0134-50



The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

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Storage¹

Store the vials in original cartons at 20 °C to 25 °C (68 °F to 77 °F). Retain in the original package to protect from bright light.

ABRAXANE is a cytotoxic drug. Follow applicable special handling and disposal procedures.

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Authorized Distributors

ABRAXANE can only be purchased through authorized distributors for administration in physician offices, hospital outpatient facilities, institutions, Veterans Affairs, and the Department of Defense. The following distributors are authorized to sell ABRAXANE and are able to service qualified accounts.

Authorized Distributor Network ²	
Specialty Distributor	
ASD Healthcare, Inc. Phone: 1-800-746-6273, Monday-Thursday, 7:00 AM-6:30 PM CT; Friday, 7:00 AM-6:00 PM CT • Fax: 1-800-547-9413 https://www.asdhealthcare.com	
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-877-453-3972, Monday-Friday, 7:00 AM-6:00 PM CT (24-hour emergency on call) • https://specialtyonline.cardinalhealth.com	
CuraScript Specialty Distribution Phone: 1-877-599-7748, Monday-Friday, 8:00 AM-7:00 PM ET • https://www.curascripts.com	
HyGen Pharmaceuticals Specialty Division 877-630-9198 • https://www.hygenpharma.com/#contactus	
McKesson Plasma and Biologics Phone: 1-877-625-2566 • Fax: 1-888-752-7626 • https://connect.mckesson.com	
McKesson Specialty Phone: 1-800-482-6700, Monday-Friday, 7:00 AM-7:00 PM CT • https://mscs.mckesson.com	
Morris & Dickson Specialty Phone: 1-800-710-6100, Monday-Friday, 8:00 AM-6:00 PM CT • Fax: 1-318-524-3096 • http://www.mdspecialtydist.com	
Oncology Supply Phone: 1-800-633-7555, Monday-Friday 8:00 AM-7:00 PM CT • https://www.oncologysupply.com	
Wholesaler	
AmerisourceBergen Corporation Phone: 1-844-222-2273 • https://abcorder.amerisourcebergen.com/	
Cardinal Health, Inc. Phone: 1-800-964-5227 • https://www.cardinalhealth.com/en/login.html	
DMS Pharmaceutical Group, Inc. Phone: 1-877-788-1100, Monday-Friday, 8:30 AM-5:00 PM CT • Fax: 1-847-518-1105 • www.dmspharma.com	
HyGen Pharmaceuticals Specialty Division 877-630-9198 • https://www.hygenpharma.com/#contactus	
McKesson Corporation Phone: 1-855-625-7385 (independent chain pharmacies) 1-855-625-6285 (retail account) 1-855-625-4677 (hospitals and health systems) • https://connect.mckesson.com	
Morris & Dickson Co., LLC Phone: 1-800-388-3833 • https://www.mdwebportal.net	
N.C. Mutual Wholesale Drug Co. Phone: 1-800-800-8551 • https://orders.mutualdrug.com	
Smith Drug Company Div Jm Smith Corporation Phone: 1-800-542-1216 • https://egate.smithdrug.com/	

Above information is accurate as of 01/24.

The ABRAXANE distribution program includes extended payment terms to Bristol Myers Squibb-authorized ABRAXANE distributors. Healthcare providers and institutions should contact their ABRAXANE distributor to understand specific payment terms that may be available to them from their distributor.

Please contact your Access & Reimbursement Manager for more details on ordering and shipping deadlines.

Please see [Important Safety Information](#) on pages 24–29 and [U.S. Full Prescribing Information](#), including **Boxed WARNING**.

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Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and the commercial payer.

Recommended HCPCS Code for ABRAXANE³

HCPCS Code	Description
J9264	Injection, paclitaxel protein-bound particles, 1 mg

Billing Unit Conversion

1 mg	1 unit	100-mg vial	100 units
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The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

It is important to note that for accurate reimbursement, any quantity of ABRAXANE that is discarded after treatment should be coded with a **JW modifier**. A JW modifier indicates unused drug or biological from a single-use vial in the event that the entire dose/quantity is not administered and the remainder is discarded.⁴

- **JZ modifier** – Starting no later than July 1, 2023, providers and suppliers are required to attest if there were no discarded amounts of drugs and biologicals⁴
- **JG modifier** – To be used by hospital outpatient to identify if the drug was obtained through 340B pricing. Note that use of this modifier will not trigger any differentiated payment⁴

Use the following claim formats when ABRAXANE is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)
- Hospital outpatient: UB-04 (CMS-1450) (paper format) or ASC 837I (electronic format)

All the coding information presented is applicable to outpatient procedures only. Please see pages 15 and 16 for more information.

Revenue Codes⁶ that may be used for administration of ABRAXANE (Hospital Use)

Revenue Code	Description
0250	General Pharmacy
0258	IV Solutions; ABRAXANE administration
0260	IV Therapy (required by Medicare for separate billable drugs)
0636	Drugs requiring detailed coding; may be used to specify ABRAXANE as the drug given

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

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Current Procedural Terminology (CPT)* Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.

The CPT codes that may be appropriate for administration of ABRAXANE appear in the table below.

Recommended CPT Codes for ABRAXANE*7

CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Please contact the payer or BMS Access Support® for additional coding information regarding ABRAXANE.

*CPT codes and descriptions only are ©2024 by American Medical Association (AMA). All rights reserved.

The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

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ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States. This version replaces the previous version, ICD-9-CM.⁸

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM diagnosis codes for the labeled indications for ABRAXANE are provided on the following pages by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support[®] at **1-800-861-0048** or visit www.BMSAccessSupport.com.

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ICD-10-CM Diagnosis Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound): Metastatic Breast Cancer

ICD-10-CM Diagnosis Codes for Metastatic Breast Cancer ⁹	
C50	Malignant neoplasm of breast
C50.0	Malignant neoplasm of nipple and areola
C50.01	Malignant neoplasm of nipple and areola, female
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.02	Malignant neoplasm of nipple and areola, male
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.1	Malignant neoplasm of central portion of breast
C50.11	Malignant neoplasm of central portion of breast, female
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.12	Malignant neoplasm of central portion of breast, male
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.2	Malignant neoplasm of upper-inner quadrant of breast
C50.21	Malignant neoplasm of upper-inner quadrant of breast, female
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.22	Malignant neoplasm of upper-inner quadrant of breast, male
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast

(continued on next page)

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ICD-10-CM Diagnosis Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound): Metastatic Breast Cancer (cont'd)

ICD-10-CM Diagnosis Codes for Metastatic Breast Cancer ⁹	
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.3	Malignant neoplasm of lower-inner quadrant of breast
C50.31	Malignant neoplasm of lower-inner quadrant of breast, female
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.32	Malignant neoplasm of lower-inner quadrant of breast, male
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.4	Malignant neoplasm of upper-outer quadrant of breast
C50.41	Malignant neoplasm of upper-outer quadrant of breast, female
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.42	Malignant neoplasm of upper-outer quadrant of breast, male
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.5	Malignant neoplasm of lower-outer quadrant of breast
C50.51	Malignant neoplasm of lower-outer quadrant of breast, female
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.52	Malignant neoplasm of lower-outer quadrant of breast, male
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast

(continued on next page)

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ICD-10-CM Diagnosis Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound): Metastatic Breast Cancer (cont'd)

ICD-10-CM Diagnosis Codes for Metastatic Breast Cancer ⁹	
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.6	Malignant neoplasm of axillary tail of breast
C50.61	Malignant neoplasm of axillary tail of breast, female
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.62	Malignant neoplasm of axillary tail of breast, male
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.8	Malignant neoplasm of overlapping sites of breast
C50.81	Malignant neoplasm of overlapping sites of breast, female
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.82	Malignant neoplasm of overlapping sites of breast, male
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.9	Malignant neoplasm of breast of unspecified site
C50.91	Malignant neoplasm of breast of unspecified site, female
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.92	Malignant neoplasm of breast of unspecified site, male
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast

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ICD-10-CM Diagnosis Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound): Advanced Non–Small Cell Lung Cancer

ICD-10-CM Diagnosis Codes for Advanced Non–Small Cell Lung Cancer ⁹	
C34.1	Malignant neoplasm of upper lobe, bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

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ICD-10-CM Diagnosis Codes for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound): Metastatic Pancreatic Adenocarcinoma

ICD-10-CM Diagnosis Codes for Metastatic Pancreatic Adenocarcinoma⁹

C25	Malignant neoplasm of pancreas
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
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

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5010 Electronic Transaction Coding for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

- For electronic transactions, including 837P and 837I, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it⁹
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter), and the quantity administered⁹

5010 Transaction Coding for ABRAXANE ^{1,10}				
How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
100 mg of paclitaxel in a single-dose vial, individually packaged in a carton	68817-0134-50	N4	UN	N468817013450UN100*

*This is an example to demonstrate NDC quantity reporting for 1 vial of ABRAXANE. The actual amount of drug used can vary based on factors such as patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

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Coding and Billing Units for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

Please contact the payer or BMS Access Support® for additional information on coding and billing units

CMS-1500 Form

The form is a standard CMS-1500 claim form. Callout A points to Box 19 (Additional Claim Information). Callout B points to Box 21 (Diagnosis or Nature of Illness or Injury). Callout C points to the shaded area above Box 24D (Date(s) of Service). Callout D points to Box 24D (Date(s) of Service). Callout E points to Box 24E (Place of Service). Callout F points to Box 24G (Billing Units).

This sample form is for informational purposes only.

Physician Office

- A** **Item 19:** Many payers require detailed information about the drug in Box 19.⁸ Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement
- B** **Item 21:** Enter the ICD-10-CM code¹⁰
- C** **Item 24A:** NDC information is required in the shaded area above the line on which a drug is reported in 24D.¹⁰ The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (UN) and the quantity administered beginning in position 14.¹⁰ For example, use "N468817013450UN100" for one 100 mg vial^{7,8}
- D** **Item 24D:** Enter the appropriate HCPCS code (J9264) and appropriate CPT code(s) for drug administration services; include modifiers, if applicable.^{3,4,10} In addition, it is required that you enter J9264-JW if necessary, on next line to record waste. Alternatively, if no wastage enter J9264-JZ to attest there were no discarded amounts⁴
- E** **Item 24E:** Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that is entered on that same line under 24D¹⁰
- F** **Item 24G:** Billing units are reported here.¹⁰ 1 mg=1 billing unit⁵

A claim for ABRAXANE should include the following⁵:

- A proper HCPCS code to define the drug and billing unit
- The quantity of billing units provided to the patient
- A CPT code that indicates how the physician administered the drug

In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity.

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Coding and Billing Units for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

UB-04 Form

The image shows a sample UB-04 form with callouts A through F pointing to specific fields:

- A:** Points to the top header section (1-4).
- B:** Points to field 49 (HCPCS/RATEL/HPIS CODE).
- C:** Points to field 45 (SERV. DATE).
- D:** Points to field 46 (SERV. UNITS).
- E:** Points to field 63 (TREATMENT AUTHORIZATION CODES).
- F:** Points to field 79 (OTHER PROCEDURE CODE).

This sample form is for informational purposes only.

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This sample form is for informational purposes only.

UB-04 is used for reimbursement of ABRAXANE administered in an institutional setting, such as a hospital, a clinic, or an ambulatory surgical center.¹¹ Providers must submit a UB-04 claim form documenting the drug administered and associated services

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Outpatient Hospital

- A** **Form Locator (FL) 42:** Enter a 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.¹¹ CMS recommends using revenue code 0636 (drugs requiring detailed coding).⁵ Refer to page 6 for list of potential revenue codes
- B** **FL 43:** Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.¹¹ For example, use "N468817013450UN100" for one 100 mg vial^{1,11}
- C** **FL 44:** Enter HCPCS code (J9264) and code for the outpatient service (and modifier[s]),* if applicable.^{3,4,11} In addition, it is required that you enter J9264-JW if necessary, on next line to record waste. Alternatively, if no wastage, enter J9264-JZ to attest there were no discarded amounts. Include the JG modifier if the drug was obtained using 340B pricing⁴
- D** **FL 46:** Billing units are called *service units* and are placed here.¹¹ 1 mg = 1 billing unit⁵
- E** **FL 67:** Enter the ICD-10-CM diagnosis code¹¹
- F** **FL 80:** Some payers require detailed information about the drug in FL 80.^{5,11} Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

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Dosage and Administration for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

IMPORTANT ADMINISTRATION INSTRUCTIONS

- DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS. ABRAXANE has different dosage and administration instructions from other paclitaxel products.
- Closely monitor the infusion site for extravasation or drug infiltration during administration. Limiting the infusion of ABRAXANE to 30 minutes may reduce the risk of infusion-related reactions.
- Consider premedication in patients who have had prior hypersensitivity reactions to ABRAXANE. Do not re-challenge patients who experience a severe hypersensitivity reaction to ABRAXANE.

Recommended Dosage for Metastatic Breast Cancer¹

After failure of combination chemotherapy for metastatic breast cancer or relapse within 6 months of adjuvant chemotherapy, the recommended regimen for ABRAXANE is 260 mg/m² administered intravenously over 30 minutes every 3 weeks.

Dose Modifications for Adverse Reactions for Metastatic Breast Cancer¹

Patients who experience severe neutropenia (neutrophils less than 500 cells/mm³ for a week or longer) or severe sensory neuropathy during ABRAXANE therapy should have dosage reduced to 220 mg/m² for subsequent courses of ABRAXANE. For recurrence of severe neutropenia or severe sensory neuropathy, additional dose reduction should be made to 180 mg/m². For Grade 3 sensory neuropathy, hold treatment until resolution to Grade 1 or 2, followed by a dose reduction for all subsequent courses of ABRAXANE.

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Dosage and Administration for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

Recommended Dosage for Non–Small Cell Lung Cancer (NSCLC)¹

The recommended dose of ABRAXANE is 100 mg/m² administered as an intravenous infusion 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.

Dosage Modifications for Adverse Reactions for NSCLC¹

- Do not administer ABRAXANE on Day 1 of a cycle until absolute neutrophil count (ANC) is at least 1500 cells/mm³ and platelet count is at least 100,000 cells/mm³
- In patients who develop severe neutropenia or thrombocytopenia, withhold treatment until counts recover to an absolute neutrophil count of at least 1500 cells/mm³ and platelet count of at least 100,000 cells/mm³ on Day 1 or to an absolute neutrophil count of at least 500 cells/mm³ and platelet count of at least 50,000 cells/mm³ on Days 8 or 15 of the cycle. Upon resumption of dosing, permanently reduce ABRAXANE and carboplatin doses as outlined in the table below
- Withhold ABRAXANE for Grade 3-4 peripheral neuropathy. Resume ABRAXANE and carboplatin at reduced doses (see table below) when peripheral neuropathy improves to Grade 1 or completely resolves

Adverse Reaction	Occurance	Weekly ABRAXANE Dose (mg/m ²)	Every 3-Week Carboplatin Dose (AUC mg/mL/min)
Neutropenic fever (ANC less than 500/mm ³ with fever >38 °C) OR Delay of next cycle by more than 7 days for ANC less than 1500/mm ³ OR ANC less than 500/mm ³ for more than 7 days	First	75	4.5
	Second	50	3
	Third	Discontinue treatment	
Platelet count less than 50,000/mm ³	First	75	4.5
	Second	Discontinue treatment	
Severe sensory neuropathy – Grade 3 or 4	First	75	4.5
	Second	50	3
	Third	Discontinue treatment	

ANC=absolute neutrophil count; AUC=area under curve

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Dosage and Administration for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

Recommended Dosage for Adenocarcinoma of the Pancreas¹

The recommended dose of ABRAXANE is 125 mg/m² administered as an intravenous infusion over 30-40 minutes on Days 1, 8, and 15 of each 28-day cycle. Administer gemcitabine immediately after ABRAXANE on Days 1, 8, and 15 of each 28-day cycle.

Dose Level Reductions for Patients With Adenocarcinoma of the Pancreas ¹		
Dose Level	ABRAXANE (mg/m ²)	Gemcitabine (mg/m ²)
Full dose	125	1000
1st dose reduction	100	800
2nd dose reduction	75	600
If additional dose reduction required	Discontinue	Discontinue

Recommended Dose Modifications for Neutropenia and/or Thrombocytopenia for Patients With Adenocarcinoma of the Pancreas

Dose Recommendation and Modifications for Neutropenia and/or Thrombocytopenia at the Start of a Cycle or Within a Cycle for Patients With Adenocarcinoma of the Pancreas				
Cycle Day	ANC (cells/mm ³)		Platelet Count (cells/mm ³)	ABRAXANE/Gemcitabine
Day 1	< 1500	OR	< 100,000	Delay doses until recovery
Day 8	500 to < 1000	OR	50,000 to < 75,000	Reduce 1 dose level
	< 500	OR	< 50,000	Withhold doses
Day 15: If Day 8 doses were reduced or given without modification:				
	500 to < 1000	OR	50,000 to < 75,000	Reduce 1 dose level from Day 8
	< 500	OR	< 50,000	Withhold doses
Day 15: If Day 8 doses were withheld:				
	>= 1000	OR	≥ 75,000	Reduce 1 dose level from Day 1
	500 to < 1000	OR	50,000 to < 75,000	Reduce 2 dose levels from Day 1
	< 500	OR	< 50,000	Withhold doses

ANC=Absolute Neutrophil Count

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Dosage and Administration for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

Recommended Dose Modifications for Other Adverse Reactions in Patients With Adenocarcinoma of the Pancreas¹

Dose Modifications for Other Adverse Reactions in Patients With Adenocarcinoma of the Pancreas		
Adverse Reaction	ABRAXANE	Gemcitabine
Febrile Neutropenia: Grade 3 or 4	Withhold until fever resolves and ANC \geq 1500; resume at next lower dose level	
Peripheral Neuropathy: Grade 3 or 4	Withhold until improves to \leq Grade 1; resume at next lower dose level	No dose reduction
Cutaneous Toxicity: Grade 2 or 3	Reduce to next lower dose level; discontinue treatment if toxicity persists	
Gastrointestinal Toxicity: Grade 3 mucositis or diarrhea	Withhold until improves to \leq Grade 1; resume at next lower dose level	

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Dosage and Administration for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

Dosage Modifications for Hepatic Impairment¹

For patients with moderate or severe hepatic impairment, reduce the starting dose of ABRAXANE as shown in the following table:

Recommendations for Starting Dose in Patients With Moderate and Severe Hepatic Impairment ¹						
	AST Levels		Bilirubin Levels	ABRAXANE Dose ^a		
				MBC	NSCLC ^c	Adenocarcinoma of Pancreas ^c
Moderate	< 10 x ULN	AND	> 1.5 to ≤ 3 x ULN	200 mg/m ^{2b}	80 mg/m ^{2b}	Not recommended
Severe	< 10 x ULN	AND	> 3 to ≤ 5 x ULN	200 mg/m ^{2b}	80 mg/m ^{2b}	Not recommended
	> 10 x ULN	OR	> 5 x ULN	Not recommended	Not recommended	Not recommended

AST=aspartate aminotransferase; MBC=metastatic breast cancer; ULN=upper limit of normal

^a Dosage recommendations are for the first course of therapy. The need for further dose adjustments in subsequent courses should be based on individual tolerance.

^b A dose increase to 260 mg/m² for patients with metastatic breast cancer or 100 mg/m² for patients with non-small cell lung cancer in subsequent courses should be considered if the patient tolerates the reduced dose for two cycles.

^c Patients with bilirubin levels above the upper limit of normal were excluded from clinical trials for pancreatic or lung cancer.



Medicare Drug Reimbursement for ABRAXANE[®] for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

Coverage of ABRAXANE by Medicare is expected to follow guidance within chapter 15 of the *Medicare Benefit Policy Manual*, which states that “the program covers drugs that are furnished ‘incident to’ a physician’s service provided that the drugs are not usually self-administered by the patients who take them.”¹³ An injectable drug or biologic is typically eligible for inclusion under the “incident to” benefit when it is FDA approved, in a form not usually self-administered, furnished by a physician, and administered by the physician or by auxiliary personnel employed by the physician and under the physician’s personal supervision.¹³ It also can be furnished by other healthcare professionals.¹³ In addition, the drug must also be reasonable and necessary for an individual patient, as well as safe and effective.¹³

What is the Medicare reimbursement allowable for ABRAXANE?

Physicians*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents 1 billing unit of ABRAXANE, which is billed for each 1 mg^{5,11†}
- The amount paid to providers is published at the beginning of each calendar quarter in “Payment Allowance Limits for Medicare Part B Drugs,”¹² which can be downloaded at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice>
- Medicare Part B will reimburse physicians 80% of the allowed price for ABRAXANE; the patient is responsible for 20% coinsurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)¹⁴

Hospital outpatient facilities*

Drugs paid separately in the hospital outpatient setting are based on 106% of average sales price (ASP), not including sequestration, for 1 billing unit for the corresponding HCPCS code. This is 1 mg for ABRAXANE.^{5,6,12†}

- The Payment Rate¹² is published each quarter at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates>

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs^{15,16}
- This prospective rate changes on October 1 each year and does not allow for drugs to be paid separately^{17,18}

* While the statutory amount that Medicare will reimburse for a Part B drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.¹⁷

† See the Centers for Medicare & Medicaid Services’ (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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Commercial Insurance Reimbursement for ABRAXANE[®] for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule¹⁹
- The fee schedules are based on the ASP or AWP, as published by a credible source,^{20,21} or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R)²²

Hospital outpatient facilities

- In this setting, reimbursement is most commonly based on percentage of charges²¹
- Alternatively, some hospitals use the same ASP or AWP methodologies typically used by physician offices²¹
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges²¹

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge^{15,16}
- There are private payers that pay on a version of the DRGs¹⁶
- There are also payers that pay on a negotiated and fixed rate per day called a “per diem.”¹⁶ There are capitated rates for inpatients as well¹⁶
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so²³

Medicaid Insurance Reimbursement for ABRAXANE

Medicaid is a joint federal-state program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Medicaid programs are established and administered by each individual state.²² Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs.²¹ Benefits for Medicaid patients should be verified to identify additional needs, such as prior authorizations.

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

WARNING: SEVERE MYELOSUPPRESSION

- Do not administer ABRAXANE therapy to patients who have baseline neutrophil counts of less than 1500 cells/mm³
- Monitor for neutropenia, which may be severe and result in infection or sepsis. Perform frequent complete blood cell counts on all patients receiving ABRAXANE

CONTRAINDICATIONS

- Baseline neutrophil counts of <1500 cells/mm³
- A history of severe hypersensitivity reactions to ABRAXANE

WARNINGS AND PRECAUTIONS

Severe Myelosuppression

- Severe myelosuppression (primarily neutropenia) is dose-dependent and a dose-limiting toxicity of ABRAXANE. In clinical studies, Grade 3-4 neutropenia occurred in 34% of patients with metastatic breast cancer (MBC), 47% of patients with non-small cell lung cancer (NSCLC), and 38% of patients with pancreatic cancer
- Monitor for severe neutropenia and thrombocytopenia by performing complete blood cell counts frequently, including prior to dosing on Day 1 (for MBC) and Days 1, 8, and 15 (for NSCLC and for pancreatic cancer)
- Do not administer ABRAXANE to patients with baseline absolute neutrophil counts (ANC) of less than 1500 cells/mm³

- In the case of severe neutropenia (<500 cells/mm³ for 7 days or more) during a course of ABRAXANE therapy, reduce the dose of ABRAXANE in subsequent courses in patients with either MBC or NSCLC
- In patients with MBC, resume treatment with every-3-week cycles of ABRAXANE after ANC recovers to a level >1500 cells/mm³ and platelets recover to a level >100,000 cells/mm³
- In patients with NSCLC, resume treatment if recommended at permanently reduced doses for both weekly ABRAXANE and every-3-week carboplatin after ANC recovers to at least 1500 cells/mm³ and platelet count of at least 100,000 cells/mm³ on Day 1 or to an ANC of at least 500 cells/mm³ and platelet count of at least 50,000 cells/mm³ on Days 8 or 15 of the cycle
- In patients with adenocarcinoma of the pancreas, withhold ABRAXANE and gemcitabine if the ANC is less than 500 cells/mm³ or platelets are less than 50,000 cells/mm³ and delay initiation of the next cycle if the ANC is less than 1500 cells/mm³ or platelet count is less than 100,000 cells/mm³ on Day 1 of the cycle. Resume treatment with appropriate dose reduction if recommended

Severe Neuropathy

- Sensory neuropathy is dose- and schedule-dependent
- If ≥ Grade 3 sensory neuropathy develops, withhold ABRAXANE treatment until resolution to Grade 1 or 2 for MBC or until resolution to ≤ Grade 1 for NSCLC and pancreatic cancer followed by a dose reduction for all subsequent courses of ABRAXANE

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

Sepsis

- Sepsis occurred in 5% of patients with or without neutropenia who received ABRAXANE in combination with gemcitabine
- Biliary obstruction or presence of biliary stent were risk factors for severe or fatal sepsis
- If a patient becomes febrile (regardless of ANC), initiate treatment with broad-spectrum antibiotics
- For febrile neutropenia, interrupt ABRAXANE and gemcitabine until fever resolves and ANC ≥ 1500 cells/ mm^3 , then resume treatment at reduced dose levels

Pneumonitis

- Pneumonitis, including some cases that were fatal, occurred in 4% of patients receiving ABRAXANE in combination with gemcitabine
- Monitor patients for signs and symptoms and interrupt ABRAXANE and gemcitabine during evaluation of suspected pneumonitis
- Permanently discontinue treatment with ABRAXANE and gemcitabine upon making a diagnosis of pneumonitis

Severe Hypersensitivity

- Severe and sometimes fatal hypersensitivity reactions, including anaphylactic reactions, have been reported
- Do not rechallenge patients who experience a severe hypersensitivity reaction to ABRAXANE with this drug
- Cross-hypersensitivity between ABRAXANE and other taxane products has been reported and may include severe reactions such as anaphylaxis. Closely monitor patients with a previous history of hypersensitivity reaction to ABRAXANE with this drug

Use in Patients With Hepatic Impairment

- The exposure and toxicity of paclitaxel can be increased in patients with hepatic impairment. Closely monitor patients with hepatic impairment for severe myelosuppression
- ABRAXANE is not recommended in patients who have a total bilirubin >5 x ULN or AST >10 x ULN
- For MBC and NSCLC, the starting dose should be reduced for patients with moderate or severe hepatic impairment
- For pancreatic adenocarcinoma, ABRAXANE is not recommended for patients with moderate to severe hepatic impairment (total bilirubin >1.5 x ULN and AST ≤ 10 x ULN)

Albumin (Human)

- ABRAXANE contains albumin (human), a derivative of human blood

Embryo-Fetal Toxicity

- Based on mechanism of action and findings in animals, ABRAXANE can cause fetal harm when administered to a pregnant woman
- Advise females of reproductive potential of the potential risk to a fetus
- Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with ABRAXANE and for at least six months after the last dose of ABRAXANE
- Advise male patients with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with ABRAXANE and for at least three months after the last dose of ABRAXANE

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

ADVERSE REACTIONS

Randomized Metastatic Breast Cancer (MBC) Study

- The most common adverse reactions (≥20%) with single-agent use of ABRAXANE vs paclitaxel injection in the MBC study are alopecia (90%, 94%), neutropenia (all cases 80%, 82%; severe 9%, 22%), sensory neuropathy (any symptoms 71%, 56%; severe 10%, 2%), abnormal ECG (all patients 60%, 52%; patients with normal baseline 35%, 30%), fatigue/asthenia (any 47%, 39%; severe 8%, 3%), myalgia/arthralgia (any 44%, 49%; severe 8%, 4%), AST elevation (any 39%, 32%), alkaline phosphatase elevation (any 36%, 31%), anemia (any 33%, 25%; severe 1%, <1%), nausea (any 30%, 22%; severe 3%, <1%), diarrhea (any 27%, 15%; severe <1%, 1%), and infections (24%, 20%), respectively
- Sensory neuropathy was the cause of ABRAXANE discontinuation in 7/229 (3%) patients
- Other adverse reactions of note with the use of ABRAXANE vs paclitaxel injection included vomiting (any 18%, 10%; severe 4%, 1%), fluid retention (any 10%, 8%; severe 0%, <1%), mucositis (any 7%, 6%; severe <1%, 0%), hepatic dysfunction (elevations in bilirubin 7%, 7%), hypersensitivity reactions (any 4%, 12%; severe 0%, 2%), thrombocytopenia (any 2%, 3%; severe <1%, <1%), neutropenic sepsis (<1%, <1%), and injection site reactions (<1%, 1%), respectively. Dehydration and pyrexia were also reported
- Renal dysfunction (any 11%, severe 1%) was reported in patients treated with ABRAXANE (n=229)
- In all ABRAXANE-treated patients (n=366), ocular/visual disturbances were reported (any 13%; severe 1%)
- Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients and included cardiac ischemia/infarction, chest

pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary emboli, and hypertension

- Cases of cerebrovascular attacks (strokes) and transient ischemic attacks have been reported

Non-Small Cell Lung Cancer (NSCLC) Study

- The most common adverse reactions (≥20%) of ABRAXANE in combination with carboplatin are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue
- The most common serious adverse reactions of ABRAXANE in combination with carboplatin for NSCLC are anemia (4%) and pneumonia (3%)
- The most common adverse reactions resulting in permanent discontinuation of ABRAXANE are neutropenia (3%), thrombocytopenia (3%), and peripheral neuropathy (1%)
- The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (24%), thrombocytopenia (13%), and anemia (6%)
- The most common adverse reactions leading to withholding or delay in ABRAXANE dosing are neutropenia (41%), thrombocytopenia (30%), and anemia (16%)
- The following common (≥10% incidence) adverse reactions were observed at a similar incidence in ABRAXANE plus carboplatin-treated and paclitaxel injection plus carboplatin-treated patients: alopecia (56%), nausea (27%), fatigue (25%), decreased appetite (17%), asthenia (16%), constipation (16%), diarrhea (15%), vomiting (12%), dyspnea (12%), and rash (10%); incidence rates are for the ABRAXANE plus carboplatin treatment group

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

- Adverse reactions with a difference of $\geq 2\%$, Grade 3 or higher, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (28%, 7%), neutropenia (47%, 58%), thrombocytopenia (18%, 9%), and peripheral neuropathy (3%, 12%), respectively
 - Adverse reactions with a difference of $\geq 5\%$, Grades 1-4, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (98%, 91%), thrombocytopenia (68%, 55%), peripheral neuropathy (48%, 64%), edema peripheral (10%, 4%), epistaxis (7%, 2%), arthralgia (13%, 25%), and myalgia (10%, 19%), respectively
 - Neutropenia (all grades) was reported in 85% of patients who received ABRAXANE and carboplatin vs 83% of patients who received paclitaxel injection and carboplatin
- ### Pancreatic Adenocarcinoma Study
- Among the most common ($\geq 20\%$) adverse reactions in the phase III study, those with a $\geq 5\%$ higher incidence in the ABRAXANE/gemcitabine group compared with the gemcitabine group are neutropenia (73%, 58%), fatigue (59%, 46%), peripheral neuropathy (54%, 13%), nausea (54%, 48%), alopecia (50%, 5%), peripheral edema (46%, 30%), diarrhea (44%, 24%), pyrexia (41%, 28%), vomiting (36%, 28%), decreased appetite (36%, 26%), rash (30%, 11%), and dehydration (21%, 11%)
 - Of these most common adverse reactions, those with a $\geq 2\%$ higher incidence of Grade 3-4 toxicity in the ABRAXANE/gemcitabine group compared with the gemcitabine group, respectively, are neutropenia (38%, 27%), fatigue (18%, 9%), peripheral neuropathy (17%, 1%), nausea (6%, 3%), diarrhea (6%, 1%), pyrexia (3%, 1%), vomiting (6%, 4%), decreased appetite (5%, 2%), and dehydration (7%, 2%)
 - Thrombocytopenia (all grades) was reported in 74% of patients in the ABRAXANE/gemcitabine group vs 70% of patients in the gemcitabine group
 - The most common serious adverse reactions of ABRAXANE (with a $\geq 1\%$ higher incidence) are pyrexia (6%), dehydration (5%), pneumonia (4%), and vomiting (4%)
 - The most common adverse reactions resulting in permanent discontinuation of ABRAXANE were peripheral neuropathy (8%), fatigue (4%), and thrombocytopenia (2%)
 - The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (10%) and peripheral neuropathy (6%)
 - The most common adverse reactions leading to withholding or delay in ABRAXANE dosing are neutropenia (16%), thrombocytopenia (12%), fatigue (8%), peripheral neuropathy (15%), anemia (5%), and diarrhea (5%)

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

- Other selected adverse reactions with a $\geq 5\%$ higher incidence for all-grade toxicity in the ABRAXANE/ gemcitabine group compared to the gemcitabine group, respectively, are asthenia (19%, 13%), mucositis (10%, 4%), dysgeusia (16%, 8%), headache (14%, 9%), hypokalemia (12%, 7%), cough (17%, 7%), epistaxis (15%, 3%), urinary tract infection (11%, 5%), pain in extremity (11%, 6%), arthralgia (11%, 3%), myalgia (10%, 4%), and depression (12%, 6%)
- Other selected adverse reactions with a $\geq 2\%$ higher incidence for Grade 3-4 toxicity in the ABRAXANE/ gemcitabine group compared to the gemcitabine group are thrombocytopenia (13%, 9%), asthenia (7%, 4%), and hypokalemia (4%, 1%)

Postmarketing Experience With ABRAXANE and Other Paclitaxel Formulations

- Severe and sometimes fatal hypersensitivity reactions. Cross-hypersensitivity between ABRAXANE and other taxanes has been reported
- Congestive heart failure, left ventricular dysfunction, and atrioventricular block. Most patients were previously exposed to cardiotoxic drugs, such as anthracyclines, or had underlying cardiac history
- Extravasation. Closely monitor the ABRAXANE infusion site for possible infiltration during drug administration

DRUG INTERACTIONS

- Caution should be exercised when administering ABRAXANE concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4

USE IN SPECIFIC POPULATIONS

Pregnancy

- Based on the mechanism of action and findings in animals, ABRAXANE can cause fetal harm when administered to a pregnant woman. Advise females of the potential risk to a fetus and to avoid becoming pregnant while receiving ABRAXANE

Lactation

- Paclitaxel and/or its metabolites were excreted into the milk of lactating rats. Nursing must be discontinued when receiving treatment with ABRAXANE and for two weeks after the last dose

Females and Males of Reproductive Potential

- Based on animal studies and mechanism of action, ABRAXANE can cause fetal harm when administered to a pregnant woman
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with ABRAXANE
- Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with and for at least six months after the last dose of ABRAXANE [see *Warnings and Precautions*]
- Advise males with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with ABRAXANE and for at least three months after the last dose of ABRAXANE [see *Warnings and Precautions*]

(continued on next page)

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Important Safety Information for ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) (cont'd)

- Based on findings in animals, ABRAXANE may impair fertility in females and males of reproductive potential

Pediatric

- The safety and effectiveness of ABRAXANE in pediatric patients have not been established

Geriatric

- A higher incidence of epistaxis, diarrhea, dehydration, fatigue, and peripheral edema was found in patients 65 years or older who received ABRAXANE for MBC in a pooled analysis of clinical studies
- Myelosuppression, peripheral neuropathy, and arthralgia were more frequent in patients ≥ 65 years of age treated with ABRAXANE and carboplatin in NSCLC
- Diarrhea, decreased appetite, dehydration, and epistaxis were more frequent in patients 65 years or older compared with patients younger than 65 years old who received ABRAXANE and gemcitabine in adenocarcinoma of the pancreas

Renal Impairment

- There are insufficient data to permit dosage recommendations in patients with severe renal impairment or end stage renal disease (estimated creatinine clearance < 30 mL/min)

DOSAGE AND ADMINISTRATION

- DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS
- Dose reductions or discontinuation may be needed based on severe hematologic, neurologic, cutaneous, or gastrointestinal toxicity

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