

POLICY AND PROCEDURE

DEPARTMENT: Pharmacy	DOCUMENT NAME: Paclitaxel, Protein Bound
PAGE: Page 1 of 15	REPLACES DOCUMENT: N/A
APPROVED DATE: 9/1/15	RETIRED: N/A
EFFECTIVE DATE: 10/12/15	REVIEWED/REVISED: N/A
PRODUCT TYPE: All	REFERENCE NUMBER: IL.PP.002

SCOPE:

This policy applies to any provider prescribing, furnishing, or administering protein-bound paclitaxel.

PURPOSE & IMPORTANT REMINDER:

This policy is current at the time of publication. Centene Corporation retains the right to change or amend this policy at any time.

This policy has been developed by licensed health care professionals and is based upon a review of currently available clinical information (including clinical outcome studies, evidence-based guidelines, and other relevant evidence). Centene Corporation makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this policy.

The purpose of this policy is to serve as one component of the guidelines used to assist in making coverage decisions and administering benefits. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), and to applicable law.

This policy does not constitute medical advice, medical treatment or medical care. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice, diagnosis and treatment of members.

Members and providers of Health Plans associated with Centene Corporation should discuss together the information in this policy. Providers referred to in this policy are independent contractors who exercise independent judgment and over whom Centene Corporation has no control or right of control. Providers are not agents or employees of Health Plans associated with Centene Corporation.

This policy is the property of Centene Corporation. Unauthorized copying, use, and distribution of this Coverage Policy or any information contained herein are strictly prohibited.

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CPT® descriptions are from current 2015 manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Centene Corporation.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this policy.

Note: To ensure consistency with Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this Policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

POLICY OVERVIEW:

In January 2005, the Food and Drug Administration (FDA) approved a solvent-free formulation of paclitaxel for the treatment of metastatic breast cancer that uses 130-nanometer albumin-bound (nab) technology (Abraxane; nab-paclitaxel). Nab-paclitaxel utilizes the natural properties of albumin to reversibly bind paclitaxel, transport it across the endothelial cell membrane, and concentrate it to the areas of the tumor, where it acts as an inhibitor of mitosis. Published reports have shown that albumin-bound paclitaxel is more effective than paclitaxel formulated as cremophor EL (CrEL, Taxol), with almost double the response rate, increased time to disease progression, and increased overall survival in second-line patients. The absence of CrEL from the formulation is associated with decreased neutropenia and rapid improvement of peripheral neuropathy with protein-bound paclitaxel, compared with CrEL-paclitaxel. For these reasons, protein-bound paclitaxel can be infused using higher doses than that achievable with CrEL-paclitaxel, with shorter infusion duration, and without the requirement for corticosteroid and anti-histamine pre-medication to reduce the risk of solvent-mediated hypersensitivity reactions (Gradishar, 2006). In January 2005, the FDA approved albumin-bound paclitaxel (Abraxane) for the treatment of metastatic breast cancer after failure of combination chemotherapy or for relapse within 6 months of adjuvant chemotherapy. In 2012, FDA approved indications added advanced non-small cell lung cancer, and in 2013, late-stage pancreatic cancer.

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The purpose of this policy is to define coverage criteria for protein-bound paclitaxel therapy to be used by IlliniCare Health Plan in making coverage decisions and administering benefits.

POLICY:

Indications

The FDA approved indications for protein-bound paclitaxel include:

- Adjuvant treatment of breast cancer;
- Locally advanced or metastatic non-small cell lung cancer;
- Metastatic adenocarcinoma of the pancreas.

The National Comprehensive Cancer Network Drug & Biologic Compendium lists the following indications for albumin-bound paclitaxel:

- Breast cancer (recurrent or metastatic) that is:
 - Hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative with visceral crisis; *or*
 - HER2-negative and either hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory; *or*
 - Progressive with no clinical benefit after 3 consecutive endocrine therapy regimens or with symptomatic visceral disease;
- Epithelial ovarian cancer (persistent or recurrent);
- Fallopian tube cancer (persistent or recurrent);
- Melanoma:
 - Incompletely resected or unresectable nodal recurrence;
 - Local/satellite and/or in-transit unresectable recurrence;
 - Recurrent or metastatic disease in persons with good performance status;
 - Unresectable stage III in-transit metastases;
- Non-small cell lung cancer (first line therapy for recurrence or metastasis in combination with carboplatin in ECOG performance status 0-2 patients);
- Non-small cell lung cancer (for individuals who have experienced hypersensitivity reactions after receiving paclitaxel or docetaxel despite pre-medication, or for individuals in whom standard hypersensitivity pre-medications are contraindicated);
- Pancreatic cancer (in combination with gemcitabine) for individuals with locally advanced unresectable or metastatic disease and good performance status;
- Primary peritoneal cancer (persistent disease or recurrence).

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Limitations/Utilization Guidelines

Although albumin-bound paclitaxel is also being studied in other types of cancers such as adrenocortical cancer, angiosarcoma, bladder cancer, cervical cancer, endometrial cancer, head and neck cancer (including squamous-cell carcinoma of the hypopharynx, oropharynx, and oral cavity), hepatocellular cancer, and prostate cancer, the effectiveness of albumin-bound paclitaxel in these cancers has not been established.

Covered Procedure Codes

The following is a list of procedures codes for which coverage may be provided when billed with a diagnosis code(s) that supports coverage criteria (see list of ICD codes supporting coverage criteria further below).

CPT/HCPCS Code	Descriptor
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration; each additional hour (List separately in addition to code for primary procedure)
J9264	Injection, paclitaxel protein-bound particles, 1 mg

Non-covered Procedure Codes

The following is a list of procedures codes for which coverage is NOT provided, unless an exception is noted in this policy.

CPT/HCPCS Code	Descriptor
Not Applicable	

ICD-9-CM Diagnosis Codes That Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-9-CM Code	Descriptor
157.0	Malignant neoplasm of head of pancreas
157.1	Malignant neoplasm of body of pancreas
157.2	Malignant neoplasm of tail of pancreas
157.3	Malignant neoplasm of pancreatic duct
157.8	Malignant neoplasm of other specified sites of pancreas

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ICD-9-CM Code	Descriptor
157.9	Malignant neoplasm of pancreas, part unspecified
158.8	Malignant neoplasm of specific parts of peritoneum
158.9	Malignant neoplasm of peritoneum, unspecified
162.2	Malignant neoplasm of main bronchus
162.3	Malignant neoplasm upper lobe, bronchus or lung
162.4	Malignant neoplasm middle lobe, bronchus or lung
162.5	Malignant neoplasm lower lobe, bronchus or lung
162.8	Malignant neoplasm other parts of bronchus or lung
162.9	Malignant neoplasm bronchus and lung, unspecified
172.0	Malignant melanoma of lip
172.1	Malignant melanoma of eyelid, including canthus
172.2	Malignant melanoma of ear and external auditory canal
172.3	Malignant melanoma of other and unspecified part of face
172.4	Malignant melanoma of scalp and neck
172.5	Malignant melanoma of trunk, except scrotum
172.6	Malignant melanoma of upper limb, including shoulder
172.7	Malignant melanoma of lower limb, including hip
172.8	Malignant melanoma of other specified sites of skin
172.9	Malignant melanoma of skin, site unspecified
174.0	Malignant neoplasm of female breast, nipple and areola
174.1	Malignant neoplasm of female breast, central portion
174.2	Malignant neoplasm of female breast, upper-inner quadrant
174.3	Malignant neoplasm of female breast, lower-inner quadrant
174.4	Malignant neoplasm of female breast, upper-outer quadrant
174.5	Malignant neoplasm of female breast, lower-outer quadrant
174.6	Malignant neoplasm of female breast, axillary tail
174.8	Malignant neoplasm of other specified sites of female breast
174.9	Malignant neoplasm of breast (female), unspecified
175.0	Malignant neoplasm of male breast, nipple and areola
175.9	Malignant neoplasm of other and unspecified sites of male breast
183.0	Malignant neoplasm of ovary
183.2	Malignant neoplasm of Fallopian tube
183.3	Malignant neoplasm of broad ligament
183.4	Malignant neoplasm of parametrium
183.5	Malignant neoplasm of round ligament
183.8	Malignant neoplasm of other specified sites of uterine adnexa

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ICD-9-CM Code	Descriptor
183.9	Malignant neoplasm of uterine adnexa, unspecified

ICD-9-CM Diagnosis Codes That DO NOT Support Coverage Criteria

The following is a list of diagnosis codes for which coverage is NOT provided, unless an exception is noted in this policy.

ICD-9-CM Code	Descriptor
Not Applicable	

ICD-10-CM Diagnosis Codes That Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-10-CM Code	Descriptor
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	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
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
C34.30	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
C34.80	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

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ICD-10-CM Code	Descriptor
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
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
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	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.121	Malignant neoplasm of central portion of right male breast

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ICD-10-CM Code	Descriptor
C50.122	Malignant neoplasm of central portion of left male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs

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ICD-10-CM Code	Descriptor
C57.8	Malignant neoplasm of overlapping sites of female genital organs
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs
Z85.820	Personal history of malignant melanoma of skin

ICD-10-CM Diagnosis Codes That DO NOT Support Coverage Criteria

The following is a list of diagnosis codes for which coverage is NOT provided, unless an exception is noted in this policy.

ICD-10-CM Code	Descriptor
Not Applicable	

PROCEDURE: NOT APPLICABLE

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POLICY AND PROCEDURE

DEPARTMENT: Pharmacy	DOCUMENT NAME: Paclitaxel, Protein Bound
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DEFINITIONS:

ECOG/WHO/Zubrod score

The Eastern Cooperative Oncology Group (ECOG) score (published by Oken *et al.* in 1982), also called the WHO or Zubrod score (after C. Gordon Zubrod), runs from 0 to 5, with 0 denoting perfect health and 5 death: Its advantage over the Karnofsky scale lies in its simplicity.

- 0 – Asymptomatic (Fully active, able to carry on all predisease activities without restriction)
- 1 – Symptomatic but completely ambulatory (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature. For example, light housework, office work)
- 2 – Symptomatic, <50% in bed during the day (Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours)
- 3 – Symptomatic, >50% in bed, but not bedbound (Capable of only limited self-care, confined to bed or chair 50% or more of waking hours)
- 4 – Bedbound (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)
- 5 – Death

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POLICY AND PROCEDURE APPROVAL

POLICY HISTORY	
9/1/15- 10/12/15	Notice Period
10/12/15	Original Effective Date

The electronic approval retained in Compliance 360

Chief Medical Officer:

Approval on file