

Paclitaxel, albumin-bound (Abraxane[®])

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Paclitaxel, albumin-bound (Abraxane®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at <http://www.cms.gov> for additional information.

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

Paclitaxel, albumin-bound (Abraxane): Discussion

Paclitaxel protein-bound particles belong to a group of drugs referred to as taxanes, which are anti-microtubule agents. Paclitaxel protein-bound particles produce anti-cancer effects by causing abnormalities in microtubule formation in cells. Microtubules are components of cells that provide a structural framework that enables cells to divide and grow. The abnormal microtubule formation caused by paclitaxel protein-bound particles inhibits cellular replication and ultimately causes cellular death. Paclitaxel protein-bound particles are unique in that the active form of the drug is bound with albumin, which is a type of protein normally found in the human body. This form of paclitaxel delivers high concentrations of the active ingredient into the cancer cells and reduces the incidence of side effects compared to the original form of the drug.¹

Paclitaxel is a microtubule inhibitor that 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.

Paclitaxel is associated with a few adverse reactions including severe myelosuppression, neuropathy, sepsis, pneumonitis, severe hypersensitivity, use in patients with hepatic impairment and embryo-fetal toxicity.

Paclitaxel is approved by the Food and Drug Administration (FDA) for the treatment of patients with following cancer types: breast, non-small cell lung and pancreatic adenocarcinoma.²

The National Comprehensive Cancer Network (NCCN) endorses paclitaxel, albumin-bound in the following cancer types: ampullary adenocarcinoma, biliary tract cancers, breast cancer, cervical cancer, Kaposi sarcoma, cutaneous melanoma, uveal melanoma, non-small cell lung cancer, ovarian/fallopian tube, primary peritoneal cancer, pancreatic cancer, small bowel adenocarcinoma, and uterine neoplasms.^{3,4,5,6,7,8,9,10,11,12,13,14}

Paclitaxel, albumin-bound: Definitions

- **BRAF- V600E mutation** - BRAF is a serine/threonine kinase that is part of the MAP/ERK signaling pathway.⁷ Mutations in the gene lead to unrestrained cell growth and proliferation. BRAF mutations are most commonly found in the 600th codon (V600), most frequently V600E (80%) but also including V600K (15%) and a few others. BRAF V600 mutations are associated with sensitivity to BRAF inhibitors and MEK inhibitors in melanoma.² BRAF mutations are most commonly associated with melanoma and NSCLC. The BRAF V600E mutation occurs in 1-2% of patients with lung adenocarcinoma; it is the most common of the BRAF point mutations when considered against all tumor types. Mutations in BRAF typically do not overlap with EGFR and MET exon 14 skipping mutations, RET rearrangements, ALK rearrangements, and ROS1 rearrangements.¹⁵
- **Cancer Antigen CA 19-9** - Cancer antigen 19-9 (CA 19-9) is a protein found in the blood. When found at elevated levels, CA 19-9 may indicate the presence of certain types of cancers or noncancerous conditions. This test is used alongside other types of testing, such as imaging, to help diagnose disease, monitor a patient's response to treatment, and assist in detecting the return of a disease after treatment.¹⁶
- **Carcinoembryonic antigen (CEA)** - CEA is a protein that is a type of "tumor marker." Tumor markers are substances that are often made by cancer cells or by normal cells in response to cancer.¹⁷
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **Human epidermal growth factor receptor 2 (HER-2)** - HER2 breast cancer is a breast cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2). This protein promotes the growth of cancer cells. In about 1 of every 5 breast cancers, the cancer cells have extra copies of the gene that makes the HER2 protein. HER2-positive breast cancers tend to be more aggressive than other types of breast cancer.¹⁸
- **National Comprehensive Cancer Network (NCCN)** - An alliance of more than thirty leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Programmed cell death protein 1 (PD-1)/Programmed cell death-ligand 1 (PD-L1)** - Checkpoint proteins, such as PD-L1 on tumor cells and PD-1 on T-cells, help keep immune responses in check. The binding of PD-L1 to PD-1 keeps T cells from killing tumor cells in the body. Blocking the binding of PD-L1 to PD-1 with an immune checkpoint inhibitor (anti-PD-L1 or anti-PD-1) allows the T cells to kill tumor cells.¹⁹

Paclitaxel, albumin-bound: Policy

Note: Coverage of paclitaxel, albumin-bound will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Paclitaxel, albumin-bound will be considered for coverage when the following criteria are met:

Ampullary Adenocarcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Neoadjuvant therapy with or without subsequent chemoradiation in combination with gemcitabine for pancreatobiliary and mixed type for localized disease in high-risk patients (i.e., imaging findings, markedly elevated CA 19-9, markedly elevated carcinoembryonic antigen (CEA), large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); OR
4. First-line therapy for pancreatobiliary and mixed-type disease in combination with gemcitabine for patients with good performance status (PS) defined as (ECOG 0-1, good biliary drainage, and adequate nutritional intake); OR to be considered in patients with poor performance status and ECOG PS 2 for one of the following:
 - a) Unresectable localized disease
 - b) Stage IV resected ampullary cancer
 - c) Metastatic disease at initial presentation; OR
5. Subsequent therapy in combination with gemcitabine for disease progression in patients with good performance status (ECOG 0-1, good biliary drainage and adequate nutritional intake) and pancreatobiliary and mixed-type disease if previously treated with fluoropyrimidine-based therapy; OR
6. Disease progression in select patients (poor performance status (PS) and ECOG PS 2) with pancreatobiliary and mixed type in combination with gemcitabine.⁴

Gallbladder Cancer- Biliary Tract Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Neoadjuvant chemotherapy in combination with gemcitabine for resectable locally advanced disease that presents as one of the following:

- a) Incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable
 - b) Incidental finding on pathologic review
 - c) Mass on imaging
 - d) Jaundice; OR
4. Primary treatment for unresectable or resected gross residual (R2) disease, or metastatic disease in combination with gemcitabine.⁴

Intrahepatic and Extrahepatic Cholangiocarcinoma - Biliary Tract Cancer

- 1. At least 18 years of age; AND
- 2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

- 3. Gemcitabine with or without cisplatin for one of the following:
 - a) Primary treatment for unresectable or resected gross residual (R2) disease, unresectable or metastatic disease
 - b) Subsequent treatment for progression on or after systemic treatment for unresectable or resected gross residual (R2) disease, or metastatic disease.⁵

Invasive and Inflammatory Breast Cancer

- 1. At least 18 years of age; AND
- 2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

- 3. 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; OR

For **NCCN** required criteria coverage:

- 4. Single agent therapy or in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis for one of the following:
 - a) Recurrent unresectable (local or regional) or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-negative disease that is hormone receptor-positive with visceral crisis or endocrine therapy refractory as one of the following:
 - i. First-line therapy if no germline BRCA 1/2 mutation
 - ii. Second-line therapy if not a candidate for fam trastuzumab deruxtecan-nxki
 - iii. Third-line therapy and beyond
 - b) Recurrent unresectable (local or regional) or stage IV (M1) triple-negative breast cancer (TNBC) as one of the following:
 - i. First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation
 - ii. Second-line therapy
 - iii. Third-line therapy or beyond; OR

5. Fourth-line therapy and beyond in combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable (local or regional) or stage IV (M1) disease that is one of the following:
 - a) Hormone receptor-negative
 - b) Hormone receptor-positive with or without endocrine therapy; OR
6. Therapy in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥ 10) triple-negative recurrent unresectable (local or regional) or stage IV (M1) disease for one of the following:
 - a) First-line therapy
 - b) Second and subsequent lines of therapy if PD-1/PD-L1 inhibitor has not been previously used; OR
7. May be substituted for other taxanes (paclitaxel or docetaxel) in select patients due to medical necessity (E.g., hypersensitivity reaction).⁶

Cervical Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Subsequent therapy as a single agent for one of the following:
 - a) Local/regional recurrence
 - b) Stage IVB or distant metastases
 - c) Persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC).⁷

Kaposi Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Subsequent therapy for those that are intolerant to paclitaxel, given alone (no HIV) or with antiretroviral therapy (ART) for people with HIV (PWH), for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease that has progressed on or not responded to first-line systemic therapy, and progressed on alternate first-line systemic therapy.⁸

Cutaneous Melanoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy as a single agent or in combination with carboplatin for metastatic or unresectable disease.⁹

Uveal Melanoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Single-agent therapy for metastatic or unresectable disease.¹⁰

Non-Small Cell Lung Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. First-line treatment in combination with carboplatin, in locally advanced or metastatic patients who are not candidates for curative surgery or radiation therapy²; OR

For **NCCN** required criteria coverage:

4. First-line therapy for recurrent, advanced, or metastatic disease with PD-L1 expression positive ($\geq 1\%$) tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2 in combination with one of the following:
 - a) Pembrolizumab and carboplatin for squamous cell histology
 - b) Carboplatin and atezolizumab for nonsquamous cell histology
 - c) Tremelimumab-actl, durvalumab, and carboplatin; OR
5. Treatment for recurrent, advanced, or metastatic disease in combination with one of the following:
 - a) Carboplatin for those with performance status (PS) 0-2 if contraindications to PD-1 or PD-L1 inhibitors and PS 0-1 for both nonsquamous cell histology and squamous cell histology, or other recommended regimen for nonsquamous cell histology and PS 2, or preferred for squamous cell histology and PS 2)
 - b) Single agent for PS 2 for both nonsquamous cell histology and squamous cell histology)
 - c) The above regimens are used for one of the following:
 - i. Initial systemic therapy for PD-L1 expression positive ($\geq 1\%$) and negative for actionable molecular biomarkers with contraindications to PD-1 or PD-L1 inhibitors

- ii. Initial systemic therapy for PD-L1 <1% and negative for actionable molecular biomarkers
 - iii. First-line therapy for EGFR exon 20 mutation positive tumors
 - iv. First-line therapy for KRAS G12C mutation positive tumors
 - v. First-line or subsequent therapy for BRAF V600E mutation positive tumors
 - vi. First-line or subsequent therapy for NTRK1/2/3 gene fusion positive tumors
 - vii. First-line or subsequent therapy for MET exon 14 skipping mutation positive tumors
 - viii. First-line or subsequent therapy for RET rearrangement positive tumors
 - ix. First-line therapy for ERBB2 (HER2) mutation positive tumors
 - x. Subsequent therapy for EGFR exon 19 deletion or exon 21 L858R tumors and prior erlotinib +/- (ramucirumab or bevacizumab), afatinib, gefitinib, osimertinib, or dacomitinib therapy
 - xi. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy
 - xii. Subsequent therapy for ALK rearrangement positive tumors and prior crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib therapy
 - xiii. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, or ceritinib therapy
 - xiv. Subsequent therapy for PD-L1 expression positive ($\geq 1\%$) tumors and negative for actionable molecular biomarkers after prior PD-1/PD-L1 inhibitor but no prior platinum-containing chemotherapy; OR
6. Treatment for recurrent, advanced, or metastatic disease for patients with performance status (PS) 0-1 and no contraindications to PD-1 or PD-L1 inhibitors, in combination with one of the following:
- a) Atezolizumab and carboplatin for nonsquamous cell histology
 - b) Carboplatin and pembrolizumab for squamous cell histology
 - c) Tremelimumab-actl, durvalumab, and carboplatin
 - d) The above regimens are used for one of the following:
 - i. Initial systemic therapy for PD-L1 <1% and negative for actionable molecular biomarkers
 - ii. First-line therapy for EGFR exon 20 mutation positive tumors
 - iii. First-line therapy for KRAS G12C mutation positive tumors
 - iv. First-line or subsequent therapy for BRAF V600E mutation positive tumors
 - v. First-line or subsequent therapy for NTRK1/2/3 gene fusion positive tumors
 - vi. First-line or subsequent therapy for MET exon 14 skipping mutation positive tumors
 - vii. First-line or subsequent therapy for RET rearrangement positive tumors
 - viii. First-line therapy for ERBB2 (HER2) mutation positive tumors
 - ix. Subsequent therapy for EGFR exon 19 deletion or exon 21 L858R tumors and prior erlotinib +/- (ramucirumab or bevacizumab), afatinib, gefitinib, osimertinib, or dacomitinib therapy
 - x. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy

- xi. Subsequent therapy for ALK rearrangement positive tumors and prior crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib therapy
- xii. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, or ceritinib therapy; OR

Note:

1. If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.
 2. Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (i.e., EGFR exon 19 deletion or exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.
7. Single agent (if not already given) as subsequent systemic therapy for recurrent, advanced, or metastatic disease in those with performance status 0-2; OR
8. May be substituted for either paclitaxel or docetaxel in those who have experienced hypersensitivity reactions after receiving paclitaxel or docetaxel despite premedication, or for those in whom standard hypersensitivity premedication is contraindicated.¹¹

Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

(Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma [malignant mixed Müllerian tumors], clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Single-agent therapy for persistent disease or recurrence for one of the following:
 - a) As immediate treatment for serially rising CA-125 in patients who previously received chemotherapy
 - b) For progression on primary, maintenance, or recurrence therapy (platinum-resistant disease)
 - c) For stable or persistent disease (if not on maintenance therapy) (platinum-resistant disease)
 - d) For complete remission and relapse <6 months after completing chemotherapy (platinum-resistant disease)

- e) For radiographic and/or clinical relapse in patients with previous complete remission and relapse ≥ 6 months after completing prior chemotherapy (platinum-sensitive disease); OR
- 4. In combination with carboplatin if persistent disease or recurrence for patients with confirmed taxane hypersensitivity for one of the following:
 - a) As immediate treatment for serially rising CA-125 in patients that previously received chemotherapy (platinum-sensitive or platinum-resistant)
 - b) For progression on primary, maintenance, or recurrence therapy (platinum-resistant)
 - c) For stable or persistent disease (if not on maintenance therapy) (platinum-resistant)
 - d) For complete remission and relapse < 6 months after completing chemotherapy (platinum-resistant)
 - e) In patients with complete remission and relapse ≥ 6 months after completing prior chemotherapy (platinum-sensitive); OR

Note: For platinum-resistant disease, do not use in platinum-refractory disease.

- 5. May be a substitute for paclitaxel in patients who experience a hypersensitivity reaction to paclitaxel.

Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer/Low-Grade Serous Carcinoma

- 1. At least 18 years of age; AND
- 2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

- 3. Single agent therapy for platinum-sensitive or platinum-resistant recurrence; OR
- 4. In combination with carboplatin if platinum-sensitive or platinum-resistant (do not use in platinum-refractory disease) recurrence for patients with confirmed taxane hypersensitivity; OR
- 5. May be a substitute for paclitaxel in patients who experience a hypersensitivity reaction to paclitaxel.¹²

Pancreatic Adenocarcinoma

- 1. At least 18 years of age; AND
- 2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

- 3. First-line therapy for metastatic disease, in combination with gemcitabine²; OR

For **NCCN** required criteria coverage:

4. Neoadjuvant therapy in combination with gemcitabine with or without subsequent chemoradiation for one of the following:
 - a) Resectable disease
 - b) Biopsy-positive borderline resectable disease; OR
5. First-line therapy, or as induction therapy followed by chemoradiation for locally advanced disease and good performance status defined as (ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) in combination with one of the following:
 - a) Gemcitabine
 - b) Gemcitabine and cisplatin; OR
6. First-line therapy, or as induction therapy followed by chemoradiation for locally advanced disease and intermediate performance status (ECOG PS 2) in combination with gemcitabine; OR
7. First-line therapy for metastatic disease with good performance status defined as (ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) in combination with:
 - a) Gemcitabine
 - b) Gemcitabine and cisplatin; OR
8. First-line therapy for metastatic disease with intermediate performance status (ECOG PS 2) in combination with gemcitabine; OR
9. First-line therapy, or as induction therapy followed by chemoradiation for locally advanced disease and intermediate performance status (ECOG PS 2) in combination with gemcitabine; OR
10. Subsequent therapy for locally advanced or metastatic disease and disease progression if good performance status is defined as (ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) and previously treated with fluoropyrimidine-based therapy in combination with one of the following:
 - a) Gemcitabine
 - b) Gemcitabine and cisplatin; OR
11. Subsequent therapy for locally advanced or metastatic disease and disease progression if intermediate performance status (ECOG PS 2) and previously treated with fluoropyrimidine-based therapy in combination with gemcitabine; OR
12. Maintenance therapy for metastatic disease (if previous first-line gemcitabine and albumin-bound paclitaxel), if good performance status (ECOG PS 0-1) or intermediate PS (ECOG PS 2), and no disease progression in combination with gemcitabine; OR
13. Therapy, if greater than or equal to 6 months from completion of primary therapy, in combination with one of the following:
 - a) Gemcitabine as repeat systemic therapy previously administered, or as alternative systemic therapy not previously used and performance status (ECOG PS 0-2)
 - b) Gemcitabine and cisplatin with ECOG PS 0-1; AND
 - c) The regimens above are used for one of the following:
 - i. With (if not previously done) or without chemoradiation for local recurrence in the pancreatic operative bed after resection
 - ii. Recurrent metastatic disease with or without local recurrence after resection; OR

14. Therapy if less than 6 months from completion of primary therapy and previously treated with fluoropyrimidine-based therapy in combination with one of the following:
 - a) Gemcitabine with a good performance status (ECOG PS 0-1) or an intermediate performance status (ECOG 0-2)
 - b) Gemcitabine and cisplatin with ECOG 0-1; AND
 - c) The regimens above are used for one of the following:
 - i. With (if not previously done) or without chemoradiation for local recurrence in the pancreatic operative bed after resection
 - ii. Recurrent metastatic disease with or without local recurrence after resection.¹³

Small Bowel Adenocarcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Single agent or in combination with gemcitabine for advanced or metastatic disease one of the following:
 - a) Initial therapy if patient received previous FOLFOX/CAPEOX in the adjuvant setting within past 12 months or contraindication
 - b) Second line and subsequent therapy.¹⁴

Uterine Neoplasms (endometrial carcinoma)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Second-line or subsequent therapy as a single agent for recurrent disease for one of the following:
 - a) Isolated metastases
 - b) Disseminated metastases with or without sequential palliative external beam radiation therapy (EBRT)
 - c) Sequential EBRT and with or without brachytherapy for locoregional recurrence in patients with no prior RT to the site of recurrence, or previous vaginal brachytherapy only
 - d) After surgical exploration, with sequential EBRT for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissue, or in pelvic, para-aortic lymph nodes
 - e) After surgical exploration, with or without sequential EBRT for locoregional recurrence in patients with upper abdominal or peritoneal disease
 - f) With or without sequential palliative EBRT or brachytherapy for locoregional recurrence in patients who have received prior EBRT to the site of recurrence.¹⁵

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Paclitaxel, albumin-bound: References

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Paclitaxel albumin - bound: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C17.9	Malignant neoplasm of small intestine, unspecified
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C25.1	Malignant neoplasm of body of the pancreas
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C46.9	Kaposi's sarcoma, unspecified
C48.2	Malignant neoplasm of peritoneum, unspecified
C50.919	Malignant neoplasm breast - invasive
C54.1	Malignant neoplasm of endometrium

C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
J9264	Paclitaxel, albumin bound (Abraxane)

Paclitaxel, albumin bound: Revision and Review History

No.	Description	DATE(S)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	10/2/2023, 11/11/2024
3	Policy Revision Dates:	11/11/2024
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	11/16/2023, 11/20/2024
6	Revision Changes:	11/11/2024 - Added adverse reactions, one indication for ampullary, and one indication for pancreatic adenocarcinoma