# Medical Policy:

## Abraxane® (paclitaxel protein-bound particles) Intravenous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.66 | February 13, 2025 | |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Abraxane is albumin-bound paclitaxel exhibiting its action as a microtubule inhibitor preventing microtubule depolymerization necessary for interphase and mitotic functions in the cells.

## Length of Authorization

Coverage will be provided for six months and may be renewed, unless otherwise specified

- Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin OR in combination with pembrolizumab and carboplatin: Coverage will be provided for up to a maximum of 12 weeks of therapy (12 doses) and may NOT be renewed.
- Non-Small Cell Lung Cancer (NSCLC) in combination with atezolizumab and carboplatin: Coverage will be provided for up to a maximum of 18 weeks of therapy (18 doses) and may NOT be renewed.
- Neoadjuvant therapy for Ampullary Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.
- Neoadjuvant therapy for Gallbladder cancer: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.

- Neoadjuvant and induction therapy in combination with gemcitabine for Pancreatic Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

Kaposi Sarcoma

- 300 billable units per 28 days

NSCLC

- 900 billable units per 21 days

Cervical Cancer, Biliary Tract Cancers, Vaginal Cancer, & Ampullary Adenocarcinoma

- 900 billable units per 28 days

Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, Ovarian Cancer, Fallopian Tube & Primary Peritoneal Cancer, Endometrial Carcinoma

- 2800 billable units per 84 days

Cutaneous & Uveal Melanoma

- 1200 billable units per 28 days

**I. INITIAL APPROVAL CRITERIA**

****For Medicare members – Abraxane-please refer to our separate LCD/NCD Medicare criteria**

Coverage is provided in the following conditions:

- Patient is 18 years of age or older; **AND**

**1. Breast cancer †**

A. Patient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy; **AND**

i. Previous chemotherapy included an anthracycline unless clinically contraindicated-**OR**

B. Patient's disease is recurrent or metastatic **OR** inflammatory breast cancer with no response to preoperative systemic therapy; **AND**:

i. Disease is HER2-negative; **AND**

a) Used as a single agent OR in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; **AND**

b) Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis; **AND**

c) Used in one of the following treatment settings:

(1) First-line therapy if no germline BRCA 1/2 mutation

(2) Second-line therapy if not a candidate for fam-trastuzumab-deruxtecan-nxki

(3) Third-line therapy and beyond; **OR**

d) Patient has triple negative breast cancer (TNBC) Ψ; **AND**

(1) Used as a single agent **OR** in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; **AND**

a.) Used in one of the following treatment settings:

- First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation
- Subsequent therapy; **OR**

b.) Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease**; OR**

e) Patient has HER2-positive disease**; AND**

(1) Used as fourth-line therapy and beyond in combination with trastuzumab; **OR**

C. May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication‡

**2. Non-small cell lung cancer †**

A. Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy †; **OR**

B. May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; **OR**

C. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**

i. Used as first-line therapy; **AND**

a. Used in one of the following:

(1) Patients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 < 1%

(2) Patients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 expression positive tumors (≥1%)

(3) Patients with PS of 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); **AND**

b. Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**

c. Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**

d. Used in combination with tremelimumab-actl, durvalumab, and carboplatin (*excluding use in patients with PD-L1 ≥50%)*; **OR**

ii. Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); **AND**

a. Used in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 ≥1%; **OR**

b. Used in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 <1%; **OR**

c. Used in patients who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **OR**

D. Used as subsequent therapy; **AND**

iv. Used as a single-agent (if not previously given) in patients with a PS 0-2; **AND**

a. Used for first progression after initial systemic therapy; **OR**

v. Used in one of the following:

a) Patients with PS of 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement

b) Patients with PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; AND

a. Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**

b. Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**

c. Used in combination with tremelimumab-actl, durvalumab, and carboplatin; **OR**

vi. Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); **AND**

a. Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **OR**

b. Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **OR**

c. Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy

** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, RET rearrangement, and ERBB2 (HER2) . If there is insufficient tissue to allow testing for all of the 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.*

*¥ Note: 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 (e.g., EGFR exon 19 deletion or L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors*

**3. <u>Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡</u>**

A. Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; **AND**

B. Patient's disease is recurrent or persistent; **AND**

C. Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**

i. Used as a single agent **OR** in combination with carboplatin in patients with confirmed taxane hypersensitivity; **AND**

a. Patient has platinum-resistant disease; **AND**

(1) Used for progression on primary, maintenance, or recurrence therapy; **OR**

(2) Used for stable or persistent disease if not currently on maintenance therapy; **OR**

(3) Used for relapsed disease <6 months following complete remission from prior chemotherapy; **OR**

b. Patient has platinum-sensitive disease; **AND**

(1) Used for relapse ≥6 months after complete remission from prior chemotherapy; OR

ii. Patient has recurrent low-grade serous carcinoma; **AND**

1.) Used as a single agent for platinum-sensitive or platinum-resistant disease; **OR**

2.) Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; **OR**

iii. May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication

**4. <u>Pancreatic Adenocarcinoma †</u>**

A. Must be used in combination with gemcitabine; **AND**

i. Patient's disease is locally advanced or metastatic; **AND**

1. Used as first-line therapy; **OR**
2. Used as induction therapy followed by chemoradiation (locally advanced disease only); **OR**
3. Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; **OR**

ii. Patient has recurrent disease in the pancreatic operative bed or metastatic disease, post-resection; **AND**

a. Used ≥6 months after completion of primary therapy; **OR**

b. Used <6 months from completion of primary therapy with a fluoropyrimidine-based regimen; **OR**

iii. Used as neoadjuvant therapy; **AND**

a. Patient has resectable disease; **OR**

b. Patient has biopsy positive borderline resectable disease; **OR**

B. Used in combination with gemcitabine and cisplatin; **AND**

a. Patient has metastatic disease; **AND**

b. Patient has ECOG PS 0-1; **AND**

c. Used as first-line therapy

**5. Cutaneous Melanoma ‡**

A. Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; **AND**

B. Used as subsequent therapy**; AND**

C. Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)

**6. Uveal Melanoma ‡**

A. Used as a single agent for distant metastatic disease

**7. Endometrial Carcinoma (Uterine Neoplasms) ‡**

A. Used as single agent therapy; **AND**

B. Patient has tried paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication or there is a documented medical contraindication to recommended premedication; **AND**

C. Used as subsequent therapy for recurrent disease

**8. Kaposi Sarcoma ‡**

A. Used as subsequent therapy in patients intolerant to paclitaxel; **AND**

B. Patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**

C. Disease has progressed on or not responded to first-line systemic therapy; **AND**

D. Disease has progressed on alternate first-line systemic therapy **AND**

i. Used as a single agent for patients that do not have HIV; **OR**

ii. Used in combination with antiretroviral therapy (ART) for patients with HIV

**9. Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡**

A. Used in combination with gemcitabine; **AND**

**i.** Patient has unresectable, resected gross residual (R2), or metastatic disease; **AND**

1. Used as primary treatment; **OR**
2. Use as subsequent treatment for progression on or after systemic therapy; **OR**

ii. Patient has resectable locoregionally advanced gallbladder cancer; **AND**

1. Used as neoadjuvant therapy; **AND**
    a. Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise unavailable; **OR**
    b. Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
    c. Patient has mass on imaging

**10. <u>Small Bowel Adenocarcinoma</u> ‡**

A. Patient has advanced or metastatic disease; **AND**

B. Used as single agent or in combination with gemcitabine; **AND**

i. Used as initial therapy after previous FOLFOX/CAPEOX in the adjuvant setting within past 12 months or contraindication; **OR**

ii. Used as subsequent therapy if not previously given

11. **<u>Ampullary Adenocarcinoma</u> ‡**

A. Used in combination with gemcitabine; **AND**

B. Patient has pancreatobiliary or mixed type disease; **AND**

i. Used as neoadjuvant therapy for localized disease in high-risk patients (i.e., equivocal or indeterminate 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**

ii. Used as first-line therapy for unresectable localized or metastatic disease; **OR**

iii. Used as subsequent therapy for disease progression

**12. <u>Cervical Cancer</u> ‡**

A. Used as a single agent as subsequent therapy; **AND**

i. Patient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); **OR**

ii. Patient has recurrent or metastatic disease

**13. Vaginal Cancer ‡**

A. Used as a single agent as subsequent therapy; **AND**

B. Patient has recurrent or metastatic disease

**†** FDA Approved Indication(s), **‡** Compendia recommended indication(s)

| Genomic Aberration Targeted Therapies (*not all inclusive*) § |
|---|
| EGFR S768I, L861Q, and/or G719X mutation positive tumors<br>– Afatinib<br>– Erlotinib<br>– Dacomitinib<br>– Gefitinib<br>– Osimertinib<br>– Amivantamab |
| ALK rearrangement-positive tumors<br>– Alectinib<br>– Brigatinib<br>– Ceritinib<br>– Crizotinib<br>– Lorlatinib |
| ROS1 rearrangement-positive tumors<br>– Ceritinib<br>– Crizotinib<br>– Entrectinib<br>– Lorlatinib<br>– Repotrectinib |
| BRAF V600E-mutation positive tumors<br>– Dabrafenib ± trametinib<br>– Encorafenib + binimetinib<br>– Vemurafenib |
| PD-L1 expression-positive tumors (≥50%)<br>– Pembrolizumab<br>– Atezolizumab<br>– Nivolumab + ipilimumab<br>– Cemiplimab<br>– Tremelimumab + durvalumab |

**II. RENEWAL CRITERIA**

Coverage can be renewed based upon the following criteria:

A. Patient continues to meet criteria identified above; **AND**

B. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**

C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neutrophil counts of < 1,500 cell/$mm^3$, sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions, myelosuppression, etc.

**Dosing/Administration**

| Indication | Dose |
|---|---|
| Breast Cancer | Single agent:<br>Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity<br>OR<br>Administer 100 mg/m² OR 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br><br>In combination with pembrolizumab:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br>In combination with carboplatin:<br>Administer 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity<br>In combination with trastuzumab:<br>Administer 260 mg/m² intravenously day 1 of a 21-day cycle until disease progression or unacceptable toxicity<br>OR<br>Administer 100 mg/m² OR 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br><br>***Note: If being used as a substitute for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²* |
| NSCLC | Single agent:<br>Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity<br>OR<br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br><br>In combination with carboplatin:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity<br>In combination with tremelimumab, durvalumab, and carboplatin:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles<br>In combination with pembrolizumab and carboplatin:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles<br>In combination with atezolizumab and carboplatin:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 to 6 cycles |

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| Ovarian Cancer, Fallopian Tube Cancer, & Primary Peritoneal Cancer | Single agent:<br>Administer 260 mg/m² intravenously day 1 of a 21-day cycle until disease progression or unacceptable toxicity<br><br>All other treatment settings:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| Kaposi Sarcoma | Administer 100 mg (fixed dose) intravenously days 1, 8, and 15 of a 28-day<br>cycle until disease progression or unacceptable toxicity |
| Cutaneous Melanoma | Single agent: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br>OR<br>Administer 150 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br>In combination with carboplatin:<br>Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| Uveal Melanoma | Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity OR<br>Administer 150 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| Endometrial Carcinoma | Administer 260 mg/m² intravenously on day 1 of a 21- day cycle until disease progression or unacceptable toxicity<br>OR<br>Administer 100 - 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| Cervical Cancer, Vaginal Cancer | Administer 100 - 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| Ampullary Adenocarcinoma, Biliary Tract Cancers | Neoadjuvant therapy:<br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle for 6 cycles<br>All other treatment settings:<br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |

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| Pancreatic Adenocarcinoma | <u>In combination with gemcitabine for neoadjuvant therapy:</u><br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle for 6 cycles<br><u>In combination with gemcitabine as induction therapy:</u><br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity for 4 - 6 cycles<br><u>In combination with gemcitabine for all other settings:</u><br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity<br><u>In combination with gemcitabine and cisplatin:</u><br>Administer 100 - 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity |
| Small Bowel Adenocarcinoma | <u>Single agent:</u><br>Administer 220 – 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity<br><u>In combination with gemcitabine:</u><br>Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J9264 | Injection, paclitaxel protein-bound particles, 1 mg; 1 billable unit = 1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 00480-3290-01 | Paclitaxel protein-bound part 100 mg (teva pharmaceuticals) |
| 00517-4300-01 | Paclitaxel protein-bound part 100 mg (American regent) |
| 00781-3531-91 | Paclitaxel protein-bound part 100 mg (sandoz) |
| 60505-6230-04 | Paclitaxel protein-bound part 100 mg (apotex) |
| 68817-0134-50 | Abraxane 100 mg powder for injection; single-use vial (b-m squibb us) |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| C17.0 | Malignant neoplasm of duodenum |
| C17.1 | Malignant neoplasm of jejunum |
| C17.2 | Malignant neoplasm of ileum |
| C17.3 | Meckel's diverticulum, malignant |
| C17.8 | Malignant neoplasm of overlapping sites of small intestine |
| C17.9 | Malignant neoplasm of small intestine, unspecified |
| C22.1 | Intrahepatic bile duct carcinoma |
| C23 | Malignant neoplasm of the gallbladder |

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| C24.0 | Malignant neoplasm of extrahepatic bile duct |
| C24.1 | Malignant neoplasm of ampulla of Vater |
| C24.8 | Malignant neoplasm of overlapping sites of biliary tract |
| C24.9 | Malignant neoplasm of biliary tract, unspecified |
| C25.0 | Malignant neoplasm of head of pancreas |
| C25.1 | Malignant neoplasm of body of the 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 |
| C33 | Malignant neoplasm of trachea |
| 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 or 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 |
| C34.90 | 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 |
| C43.111 | Malignant melanoma of right upper eyelid, including canthus |
| C43.112 | Malignant melanoma of right lower eyelid, including canthus |
| C43.121 | Malignant melanoma of left upper eyelid, including canthus |
| C43.122 | Malignant melanoma of left lower eyelid, including canthus |
| C43.20 | Malignant melanoma of unspecified ear and external auricular canal |
| C43.21 | Malignant neoplasm of right ear and external auricular canal |
| C43.22 | Malignant neoplasm of left ear and external auricular canal |
| C43.30 | Malignant melanoma of unspecified parts 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 |

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| 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 |
| C43.9 | Malignant melanoma of skin, unspecified |
| C46.0 | Kaposi's sarcoma of skin |
| C46.1 | Kaposi's sarcoma of soft tissue |
| C46.2 | Kaposi's sarcoma of palate |
| C46.3 | Kaposi's sarcoma of lymph nodes |
| C46.4 | Kaposi's sarcoma of gastrointestinal sites |
| C46.50 | Kaposi's sarcoma of unspecified lung |
| C46.51 | Kaposi's sarcoma of right lung |
| C46.52 | Kaposi's sarcoma of left lung |
| C46.7 | Kaposi's sarcoma of other sites |
| C46.9 | Kaposi's sarcoma, unspecified |
| 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 |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| 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 |
| C50.211 | 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 |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified 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 |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified 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 |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified 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 |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |

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| 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 |
| C50.511 | 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 |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| 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 |
| C50.911 | 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 |
| C50.921 | 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 |
| C52 | Malignant neoplasm of vagina |
| C53.0 | Malignant neoplasm of endocervix |
| C53.1 | Malignant neoplasm of exocervix |
| C53.8 | Malignant neoplasm of overlapping sites of cervix uteri |
| C53.9 | Malignant neoplasm of cervix uteri, unspecified |
| C54.0 | Malignant neoplasm of isthmus uteri |
| C54.1 | Malignant neoplasm of endometrium |
| C54.2 | Malignant neoplasm of myometrium |
| C54.3 | Malignant neoplasm of fundus uteri |
| C54.8 | Malignant neoplasm of overlapping sites of corpus uteri |
| C54.9 | Malignant neoplasm of corpus uteri, unspecified |
| C55 | Malignant neoplasm of uterus, part unspecified |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.9 | Malignant neoplasm of unspecified ovary |
| C57.00 | Malignant neoplasm of unspecified fallopian tube |
| C57.01 | Malignant neoplasm of right fallopian tube |
| C57.02 | Malignant neoplasm of left fallopian tube |
| C57.10 | Malignant neoplasm of unspecified broad ligament |

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| C57.11 | Malignant neoplasm of right broad ligament |
| C57.12 | Malignant neoplasm of left broad ligament |
| C57.20 | Malignant neoplasm of unspecified round 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 |
| C57.8 | Malignant neoplasm of overlapping sites of female genital organs |
| C57.9 | Malignant neoplasm of female genital organ, unspecified |
| C69.30 | Malignant neoplasm of unspecified choroid |
| C69.31 | Malignant neoplasm of right choroid |
| C69.32 | Malignant neoplasm of left choroid |
| C69.40 | Malignant neoplasm of unspecified ciliary body |
| C69.41 | Malignant neoplasm of right ciliary body |
| C69.42 | Malignant neoplasm of left ciliary body |
| C69.60 | Malignant neoplasm of unspecified orbit |
| C69.61 | Malignant neoplasm of right orbit |
| C69.62 | Malignant neoplasm of left orbit |
| Z85.068 | Personal history of other malignant neoplasm of small intestine |
| Z85.07 | Personal history of malignant neoplasm of pancreas |
| Z85.09 | Personal history of malignant neoplasm of other digestive organs |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung |
| Z85.3 | Personal history of malignant neoplasm |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |
| Z85.43 | Personal history of malignant neoplasm of ovary |

## Revision History

| Company(ies) | DATE | REVISION |
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| EmblemHealth & ConnectiCare | 2/13/2025 | Updated dosing limits<br>Addition of lengths of authorization: • Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin OR in combination with pembrolizumab and carboplatin: Coverage will be provided for up to a maximum of 12 weeks of therapy (12 doses) and may NOT be renewed. •Non-Small Cell Lung Cancer (NSCLC) in combination with atezolizumab and carboplatin: Coverage will be provided for up to a maximum of 18 weeks of therapy (18 doses) and may NOT be renewed.• Neoadjuvant therapy for Ampullary Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.<br>• Neoadjuvant therapy for Gallbladder cancer: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.<br>•Neoadjuvant and induction therapy in combination with gemcitabine for Pancreatic Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed. |

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| | | • Removed All indications •900 billable units per 21 days<br>Addition of NSCLC• 900 billable units per 21 days<br>Cervical Cancer, Biliary Tract Cancers, Vaginal Cancer, & Ampullary Adenocarcinoma • 900 billable units per 28 days<br>Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, Ovarian Cancer, Fallopian Tube & Primary Peritoneal Cancer, Endometrial Carcinoma • 2800 billable units per 84 days Cutaneous & Uveal Melanoma• 1200 billable units per 28 days<br>Addition of the following indications with criteria<br>**Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡**<br>A. Used in combination with gemcitabine; **AND**<br>**i.** Patient has unresectable, resected gross residual (R2), or metastatic disease; **AND**<br>1. Used as primary treatment; **OR**<br>2. Use as subsequent treatment for progression on or after systemic therapy; **OR**<br>ii. Patient has resectable locoregionally advanced gallbladder cancer; **AND**<br>1. Used as neoadjuvant therapy; **AND**<br>a. Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise unavailable; **OR**<br>b. Patient has incidental finding on pathologic review (cystic duct node positive); **OR**<br>c. Patient has mass on imaging<br>**Small Bowel Adenocarcinoma ‡**<br>A. Patient has advanced or metastatic disease; **AND**<br>B. Used as single agent or in combination with gemcitabine; **AND**<br>i. Used as initial therapy after previous FOLFOX/CAPEOX in the adjuvant setting within past 12 months or contraindication; **OR**<br>ii. Used as subsequent therapy if not previously given<br>**Ampullary Adenocarcinoma ‡**<br>A. Used in combination with gemcitabine; **AND**<br>B. Patient has pancreatobiliary or mixed type disease; **AND**<br>iv. Used as neoadjuvant therapy for localized disease in high-risk patients (i.e., equivocal or indeterminate 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** |

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| | | v. Used as first-line therapy for unresectable localized or metastatic disease; **OR**<br>vi. Used as subsequent therapy for disease progression<br>**Cervical Cancer ‡**<br>A. Used as a single agent as subsequent therapy; **AND**<br>i. Patient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); **OR**<br>ii. Patient has recurrent or metastatic disease<br>**Vaginal Cancer ‡**<br>A. Used as a single agent as subsequent therapy; **AND**<br>B. Patient has recurrent or metastatic disease |
| EmblemHealth & ConnectiCare | 5/1/2024 | Updated Dosing Limits. INITIAL APPROVAL CRITERIA: Added the statement: "**For Medicare members – Abraxane-please refer to our separate LCD/NCD Medicare criteria" Breast cancer †: Added "unless clinically contraindicated" to the following: "Previous chemotherapy included an anthracycline unless clinically contraindicated-OR "<br>Removed "one of the following from the statement: "Patient's disease is recurrent or metastatic OR inflammatory breast cancer with no response to preoperative systemic therapy; AND one of the following:"Removed: "Disease is hormone receptor-negative; OR " Changed the OR to an AND after the following: "<br>Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis; AND"<br>Added: "Used in one of the following treatment settings: First-line therapy if no germline BRCA 1/2 mutation<br>Second-line therapy if not a candidate for fam-trastuzumab-deruxtecan-nxki<br>Third-line therapy and beyond; OR Patient has triple negative breast cancer (TNBC) Ψ; AND<br>Used as a single agent OR in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; AND Used in one of the following treatment settings:<br>First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation Subsequent therapy; OR<br>Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease; OR Patient has HER2-positive disease; AND<br>Used as fourth-line therapy and beyond in combination with trastuzumab; OR"<br>Removed: "Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; OR<br>ii. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease ‡; OR"<br>Non-small cell lung cancer †<br>Removed: "Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); AND<br>Used in patients with tumors that have negative actionable molecular biomarkers*; AND PD-L1 <1% with performance status (PS) score of 0-1; OR PD-L1 expression positive (≥1%) tumors with PS 0-2; OR |

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| | | Used in patients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); OR"<br>Added: "Used in one of the following:<br>Patients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 < 1%<br>Patients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 expression positive tumors (≥1%)<br>Patients with PS of 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); AND<br>Used in combination with carboplatin and pembrolizumab for squamous cell histology; OR<br>Used in combination with carboplatin and atezolizumab for non-squamous histology; OR<br>Used in combination with tremelimumab-actl, durvalumab, and carboplatin (excluding use in patients with PD-L1 ≥50%); OR Used in one of the following: Patients with PS of 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement Patients with PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; AND "Removed: "Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of 0-1; AND Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; OR Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); AND Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; OR Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy "<br>Added: "Used in combination with carboplatin and pembrolizumab for squamous cell histology; OR Used in combination with carboplatin and atezolizumab for non-squamous histology; OR Used in combination with tremelimumab-actl, durvalumab, and carboplatin; OR Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); AND Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; OR Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular |

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| | | biomarkers* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy"<br>Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) ‡ Added: "Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; AND"<br>Added: example to the following statement: "Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); AND"<br>Added: "Used as a single agent OR in combination with carboplatin in patients with confirmed taxane hypersensitivity; AND<br>Patient has platinum-resistant disease; AND<br>Used for progression on primary, maintenance, or recurrence therapy; OR<br>Used for stable or persistent disease if not currently on maintenance therapy; OR<br>Used for relapsed disease <6 months following complete remission from prior chemotherapy; OR<br>Patient has platinum-sensitive disease; AND<br>Used for relapse ≥6 months after complete remission from prior chemotherapy; OR"Removed: "Used as a single agent; AND Patient has platinum-resistant disease; AND<br>Used for progression on primary, maintenance, or recurrence therapy; OR<br>Used for stable or persistent disease if not currently on maintenance therapy; OR<br>Used for relapsed disease <6 months following complete remission from prior chemotherapy; OR<br>Patient has platinum-sensitive disease; AND<br>Used for radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; OR<br>Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; AND<br>Used for relapse ≥6 months after complete remission from prior chemotherapy; OR"<br>Pancreatic Adenocarcinoma †<br>Removed: "unresectable: from the following: "Patient's disease is locally advanced, unresectable, or metastatic; AND" Removed:<br>"Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); OR<br>Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy (metastatic disease only); OR"<br>Removed: "with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); " from the following: " Patient has resectable disease with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); OR" Removed: "<br>Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy"<br>Cutaneous Melanoma ‡ : Removed "for disease progression" from the following: "Used as subsequent therapy for disease progression; OR;" changed the Or to AND |

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| | | Removed: “Used after maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)”<br>Added: “Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)”<br>Updated name to: Endometrial Carcinoma (Uterine Neoplasms) ‡<br>Added: “ Used as subsequent therapy for recurrent disease”<br>Removed: “ Patient has endometroid adenocarcinoma; AND<br>Used as primary treatment of disease NOT suitable for primary surgery; AND<br>Patient has suspected or gross cervical involvement (excluding patients using as chemotherapy alone); OR Patient has locoregional extrauterine disease; OR Patient has distant metastases; OR<br>Used as primary treatment of disease suitable for primary surgery; AND Used preoperatively for abdominal/pelvic confined disease; OR Patient has distant metastases; OR Used as adjuvant treatment for stage III-IV disease; OR Used for locoregional recurrence or disseminated metastases; OR<br>Patient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/dedifferentiated carcinoma; AND Used for locoregional recurrence or disseminated metastases; OR<br>Used as additional treatment of metastatic disease that is suitable for primary surgery; OR<br>Used as primary treatment of metastatic disease that is NOT suitable for primary Surgery”<br>Updated dosing chart |
| EmblemHealth & ConnectiCare | 8/14/2023 | Annual Review:<br><u>Breast cancer</u> Initial Criteria<br>Added: Patient’s disease is recurrent or metastatic “OR inflammatory breast cancer with no response to preoperative systemic therapy” and one of the following:<br>Removed “Disease is hormone receptor negative; OR<br>a. Disease is hormone receptor positive and refractory to endocrine therapy; OR<br>b. Patient has symptomatic visceral disease or visceral crisis; AND<br>iii. Disease is HER2-negative and using as single agent therapy; OR<br>iv. Disease is HER2-positive and using in combination with trastuzumab (in patients who were previously treated with trastuzumab)-OR-‡<br>v. May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedications.”<br>Added ”<br>Used as a single agent OR in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; AND<br>a. Disease is HER2-negative; AND<br>b. Disease is hormone receptor-negative; OR |

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| | | c. Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis; OR<br>vi. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; OR<br>vii. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease ‡; OR<br>F. May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication"<br><u>Non-small cell lung cancer Initial Criteria</u><br>Removed "A. Used in combination with carboplatin for disease that is locally advanced or metastatic; AND<br>B. Used as first line therapy in patients who are not candidates for curative surgery or radiation therapy; OR<br>C. Patient's disease is recurrent or metastatic; AND<br>c. Patient does not have locoregional recurrence without evidence of disseminated disease; AND<br>i. Used as a single agent in patients with a performance status score of 2; OR<br>ii. Used in combination with carboplatin in patients with a performance status score of 0-2; AND<br>➢ Used as first-line therapy for genomic tumor aberration (e.g., EGFR, ALK, ROS1, BRAF and PD-L1) negative or unknown OR BRAF V600E-mutation positive; OR<br>➢ Used as subsequent therapy for genomic tumor aberration (e.g., EGFR, BRAF V600E, ALK, ROS1, PD-L1) positive and prior targeted therapy§; OR<br>A. May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedications."<br><br>Added "Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy †; OR<br>D. May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; OR<br>E. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; AND<br>i. Used as first-line therapy; AND<br>a. Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); AND<br>b. Used in patients with tumors that have negative actionable molecular biomarkers*; AND |

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| | | 1.) PD-L1 <1% with performance status (PS) score of 0-1; OR<br>2.) PD-L1 expression positive (≥1%) tumors with PS 0-2; OR<br>c. Used in patients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); OR<br>iii. Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); AND<br>a.Used in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 ≥1%; OR<br>b. Used in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 <1%; OR<br>c. Used in patients who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); OR<br>D. Used as subsequent therapy; AND<br>iv. Used as a single-agent (if not previously given) in patients with a PS 0-2; AND<br>a. Used for first progression after initial systemic therapy; OR<br>v. Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of 0-1; AND<br>a. Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR<br>b. Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; OR<br>vi. Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L inhibitors (PS score of 0-2 ) or as a single agent (PS score of 2); AND<br>a. Used in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; OR<br>b. Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; OR<br>c. Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy<br>** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, RET rearrangement, and ERBB2 (HER2) . If there is insufficient tissue to allow* |

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| | | *testing for all of the 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.*<br>*¥ Note: 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 (e.g., EGFR exon 19 deletion or L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors"*<br><br><u>Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) Initial Criteria</u><br>Removed "Must be used as a single agent; OR<br>ii. Used in combination with carboplatin if platinum-sensitive with confirmed taxane hypersensitivity"<br>Added: "Used as a single agent; AND<br>a) Patient has platinum-resistant disease; AND<br>o Used for progression on primary, maintenance, or recurrence therapy; OR<br>o Used for stable or persistent disease if not currently on maintenance therapy; OR<br>o Used for relapsed disease <6 months following complete remission from prior chemotherapy; OR<br>b) Patient has platinum-sensitive disease; AND<br>o Used for radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; OR<br>D. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; AND<br>1.) Used for relapse ≥6 months after complete remission from prior chemotherapy; OR<br>E. Patient has recurrent low-grade serous carcinoma; AND<br>a. Used as a single agent for platinum-sensitive or platinum-resistant disease; OR<br>b. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; OR<br>F. May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication"<br><u>Pancreatic Adenocarcinoma Initial Criteria:</u><br>Removed "Patient has good performance status (defined as an ECOG PS of 0-2); AND<br>1. Used as first-line or induction therapy; OR<br>2. Used as second-line therapy after progression with a fluoropyrimidine-based therapy; OR<br>o Patient's disease is recurrent; AND<br>▪ Used as second-line therapy<br>o Patient's disease is resectable with high-risk features or borderline resectable; AND<br>▪ Used for neoadjuvant treatment"<br>Added "Used as first-line therapy; OR |

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| | | 3. Used as induction therapy followed by chemoradiation (locally advanced disease only); OR<br>4. Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; OR<br>5. Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); OR<br>6. Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy (metastatic disease only); OR<br>G. Patient has recurrent disease in the pancreatic operative bed or metastatic disease, post-resection; AND<br>a. Used ≥6 months after completion of primary therapy; OR<br>b. Used <6 months from completion of primary therapy with a fluoropyrimidine-based regimen; OR<br>H. Used as neoadjuvant therapy; AND<br>a. Patient has resectable disease with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); OR<br>b. Patient has biopsy positive borderline resectable disease; OR<br>I. Used in combination with gemcitabine and cisplatin; AND<br>a. Patient has metastatic disease; AND<br>b. Patient has ECOG PS 0-1; AND<br>1.)Used as first-line therapy; OR<br>2. ) Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy"<br><u>Name change from "Melanoma" to "Cutaneous Melanoma" Initial Criteria</u><br>Removed "Must be used as a single agent; AND<br>J. Patient's disease must be unresectable or metastatic; AND<br>a. Patient has uveal melanoma; OR<br>b. Used as second-line or later treatment; AND<br>i. Patient had disease progression or maximum clinical benefit from BRAF targeted therapies"<br>Added "Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; AND<br>ii. Used as subsequent therapy for disease progression; OR<br>iii. Used after maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)<br><u>Uveal Melanoma ‡</u><br>D. Used as a single agent for distant metastatic disease" |

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| | | Removed Bladder Cancer/Urothelial Carcinoma Indication and criteria<br>Uterine Cancer Initial Criteria<br>Removed "Patient has endometrial carcinoma; AND<br>K. Used as one of the following:<br>a. Primary treatment for metastatic or unresectable disease excluding patients with cervical involvement undergoing brachytherapy with or without external beam radiation therapy (EBRT); OR<br>b. Adjuvant treatment, excluding patients with Stage IA disease with adverse risk factors present OR Stage IB disease without adverse risk factors present OR Stage II disease; OR<br>c. Used as treatment of local-regional recurrent, progressive or disseminated metastatic disease; AND<br>L. Patient has tried generic paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedications or there is a documented medical contraindication to recommended premedications."<br>Added "Patient has tried paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication or there is a documented medical contraindication to recommended premedication; AND<br>i. Patient has endometroid adenocarcinoma; AND<br>a. Used as primary treatment of disease NOT suitable for primary surgery; AND<br>1.) Patient has suspected or gross cervical involvement (excluding patients using as chemotherapy alone); OR<br>2. )Patient has locoregional extrauterine disease; OR<br>3.)Patient has distant metastases; OR<br>b. Used as primary treatment of disease suitable for primary surgery; AND<br>1.)Used preoperatively for abdominal/pelvic confined disease; OR<br>2.)Patient has distant metastases; OR<br>c. Used as adjuvant treatment for stage III-IV disease; OR<br>d. Used for locoregional recurrence or disseminated metastases; OR<br>ii. Patient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/dedifferentiated carcinoma; AND<br>a. Used for locoregional recurrence or disseminated metastases; OR<br>b. Used as additional treatment of metastatic disease that is suitable for primary surgery; OR<br>c. Used as primary treatment of metastatic disease that is NOT suitable for primary Surgery"<br><br>Name change from "AIDS-related Kaposi Sarcoma" To Kaposi Sarcoma. Initial Criteria |

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| | | Removed "Must be used as subsequent therapy in combination with antiretroviral therapy (ART); AND<br>• Patient has relapsed/refractory advanced, cutaneous, oral, visceral, or nodal disease; AND<br>• Patient has disease progression after first-line and alternate first-line treatment"<br>Added: "Used as subsequent therapy; AND<br>i. Used as a single agent for patients that do not have HIV; OR<br>ii. Used in combination with antiretroviral therapy (ART) for patients with HIV; AND<br>E. Patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; AND<br>F. Disease has progressed on or not responded to first-line systemic therapy; AND<br>Disease has progressed on alternate first-line systemic therapy"<br>Updated dosing chart |
| EmblemHealth & ConnectiCare | 5/30/2023 | Added JCODE – J9259 Injection, paclitaxel protein-bound particles (American regent) not therapeutically equivalent to j9264, 1 mg |
| EmblemHealth & ConnectiCare | 3/17/2022 | Put on new template |
| EmblemHealth & ConnectiCare | 12/30/2020 | Annual Review |

## References


1. Abraxane [package insert]. Summit, NJ; Celgene Corporation; August 2020. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2018.
3. Teneriello, MG et al. Phase II evaluation of nanoparticle albumin-bound paclitaxel in platinum-sensitive patients with recurrent ovarian, peritoneal, or fallopian tube cancer. J Clin Oncol. 2009 Mar 20; 27(9):1426-31. Epub 2009 Feb 17.
4. Gradishar WJ, Krasnojon D, Cheporov S, et al, "Significantly Longer Progression-Free Survival With nab-paclitaxel Compared With Docetaxel as First-Line Therapy for Metastat*ic Breast Ca*ncer," *J Clin Oncol*, 2009, 27(22):3611-9.
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6. National Government Services, Inc. Local Coverage Article for Paclitaxel (e.g., Taxol®/Abraxane™) related to LCD L33394 (A52450). Centers for Medicare & Medicaid Services, Inc. Updated on 04/27/2018 with effective date of 05/03/2018. Accessed August 2018.