Medical Policy:
Abraxane® (paclitaxel protein-bound particles)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.66	August 14, 2023	

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.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

All indications

- 900 billable units per 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

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

1. <u>Breast cancer †</u>

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

i. Previous chemotherapy included an anthracycline-**OR**

B. Patient's disease is recurrent or metastatic **OR** inflammatory breast cancer with no response to preoperative systemic therapy and one of the following:

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

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

a. Disease is hormone receptor-negative; **OR**

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

ii. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; **OR**

iii. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease **‡; OR**

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 ‡

<u>2. Non-small cell lung cancer †</u>

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 combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); **AND**

b. Used in patients with tumors that have negative actionable molecular biomarkers*; **AND**

1.) PD-L1 <1% with performance status (PS) score of 0-1; **OR**

2.) PD-L1 expression positive (≥1%) tumors with PS 0-2; **OR**

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**

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 combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of 0-1; **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 L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, ALK rearrangement, or ROS1 rearrangement; **OR**

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**

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 L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, 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-doublet 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 cancer (Epithelial/Fallopian Tube/Primary Peritoneal) ‡</u>

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

B. Patient is not experiencing an immediate biochemical relapse; **AND**

i. Used as a single agent; **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 radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; **OR**

vi. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; **AND**

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

vii. 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**

viii. 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, unresectable, or metastatic; **AND**

a. Used as first-line therapy; **OR**

b. Used as induction therapy followed by chemoradiation (locally advanced disease only); **OR**

c. Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; **OR**

d. Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); **OR**

e. 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**

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 with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **OR**

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

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

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

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

1.)Used as first-line therapy; **OR**

2.) Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy

5. Cutaneous Melanoma ‡

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

i. Used as subsequent therapy for disease progression**; OR**

ii. Used after maximum clinical benefit from 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. Uterine Cancer ‡

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**

i. Patient has endometroid adenocarcinoma; **AND**

a. Used as primary treatment of disease NOT suitable for primary surgery; **AND**

1.) Patient has suspected or gross cervical involvement (excluding patients using as chemotherapy alone); **OR**

2.)Patient has locoregional extrauterine disease; **OR**

3.)Patient has distant metastases; **OR**

b. Used as primary treatment of disease suitable for primary surgery; **AND**

1.)Used preoperatively for abdominal/pelvic confined disease; **OR**

2.)Patient has distant metastases; **OR**

c. Used as adjuvant treatment for stage III-IV disease; **OR**

d. Used for locoregional recurrence or disseminated metastases; **OR**

ii. Patient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/dedifferentiated carcinoma; **AND**

c. Used for locoregional recurrence or disseminated metastases; **OR**

d. Used as additional treatment of metastatic disease that is suitable for primary surgery; **OR**

e. Used as primary treatment of metastatic disease that is NOT suitable for primary Surgery

8. <u>Kaposi Sarcoma ‡</u>

A. Used as subsequent 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; **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

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

Genomic Aberration Targeted Therapies (*not all inclusive*) §
Sensitizing EGFR mutation-positive tumors – Erlotinib – Afatinib – Gefitinib – Osimertinib
ALK rearrangement-positive tumors – Crizotinib – Ceritinib – Brigatinib – Alectinib
ROS1 rearrangement-positive tumors – Crizotinib – Ceritinib
BRAF V600E-mutation positive tumors – Dabrafenib/Trametinib
PD-L1 expression-positive tumors (≥50%) – Pembrolizumab

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	Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity **OR** 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 **NOTE: If substituted for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²
NSCLC	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity
Cutaneous Melanoma, Uveal Melanoma, & Ovarian Cancer	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 cycle until disease progression or unacceptable toxicity
Pancreatic Adenocarcinoma & Hepatobiliary Cancer	125 mg/m² days 1, 8, and 15 of a 28-day cycle
Small Bowel Adenocarcinoma	Administer 220 – 260 mg/m² intravenously every 21 days as a single agent until disease progression or unacceptable toxicity OR Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle in combination with gemcitabine until disease progression or unacceptable toxicity
Ampullary Adenocarcinoma	Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle in combination with gemcitabine until disease progression or unacceptable toxicity
All other indications	260 mg/m² every 21 days OR 100 mg/m² days 1, 8, and 15 of a 21-day cycle

Applicable Procedure Codes

Code	Description
J9264	Injection, paclitaxel protein-bound particles, 1 mg; 1 billable unit = 1 mg
J9259	Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to j9264, 1 mg

Applicable NDCs

Code	Description
68817-0134-xx	Abraxane 100 mg powder for injection; single-use vial

ICD-10 Diagnoses

Code	Description
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
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
C44.1021	Unspecified malignant neoplasm of skin of right upper eyelid, including canthus
C44.1022	Unspecified malignant neoplasm of skin of right lower eyelid, including canthus
C44.1091	Unspecified malignant neoplasm of skin of left upper eyelid, including canthus
C44.1092	Unspecified malignant neoplasm of skin of left lower eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.1221	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
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
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
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
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
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
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
C79.31	Secondary malignant neoplasm of brain
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
D03.111	Melanoma in situ of right upper eyelid, including canthus
D03.112	Melanoma in situ of right lower eyelid, including canthus
D03.121	Melanoma in situ of left upper eyelid, including canthus
D03.122	Melanoma in situ of left lower eyelid, including canthus
D09.0	Carcinoma in situ of bladder
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of another urinary tract organ
Z85.820	Personal history of malignant melanoma of skin

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/14/2023	Annual Review: Breast cancer Initial Criteria Added: 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 ii. Disease is hormone receptor positive and refractory to endocrine therapy; OR iii. Patient has symptomatic visceral disease or visceral crisis; AND C. Disease is HER2-negative and using as single agent therapy; OR D. Disease is HER2-positive and using in combination with trastuzumab (in patients who were previously treated with trastuzumab)-OR-‡ E. May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedications." Added " Used as a single agent OR in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; AND

		a. Disease is HER2-negative; AND b. Disease is hormone receptor-negative; OR c. Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis; OR iv. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; OR v. Used in combination with pembrolizumab for PD-L1 positive triple-negative disease ‡; OR 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" <u>Non-small cell lung cancer Initial Criteria</u> Removed "A. Used in combination with carboplatin for disease that is locally advanced or metastatic; AND B. Used as first line therapy in patients who are not candidates for curative surgery or radiation therapy; OR C. Patient's disease is recurrent or metastatic; AND b. Patient does not have locoregional recurrence without evidence of disseminated disease; AND i. Used as a single agent in patients with a performance status score of 2; OR ii. Used in combination with carboplatin in patients with a performance status score of 0-2; AND ➢ 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 ➢ Used as subsequent therapy for genomic tumor aberration (e.g., EGFR, BRAF V600E, ALK, ROS1, PD-L1) positive and prior targeted therapy§; OR 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." 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 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

		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 i. Used as first-line therapy; AND a. Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); AND b. Used in patients with tumors that have negative actionable molecular biomarkers*; AND 1.) PD-L1 <1% with performance status (PS) score of 0-1; OR 2.) PD-L1 expression positive (≥1%) tumors with PS 0-2; OR 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 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 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 combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of 0-1; 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 L858R tumors, EGFR S768I, L861Q, and/or G719X

		positive tumors, ALK rearrangement, or ROS1 rearrangement; OR 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 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 L858R tumors, EGFR S768I, L861Q, and/or G719X positive tumors, 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-doublet 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"* <u>Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) Initial Criteria</u> Removed "Must be used as a single agent; OR ii. Used in combination with carboplatin if platinum-sensitive with confirmed taxane hypersensitivity" Added: "Used as a single agent; 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 radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; OR ix. Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; AND 1.) Used for relapse ≥6 months after complete remission from prior chemotherapy; OR x. 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 xi. May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication" <u>Pancreatic Adenocarcinoma Initial Criteria:</u> Removed "Patient has good performance status (defined as an ECOG PS of 0-2); AND 1. Used as first-line or induction therapy; OR 2. Used as second-line therapy after progression with a fluoropyrimidine-based therapy; OR o Patient's disease is recurrent; AND ▪ Used as second-line therapy o Patient's disease is resectable with high-risk features or borderline resectable; AND ▪ Used for neoadjuvant treatment" Added "Used as first-line therapy; OR a. Used as induction therapy followed by chemoradiation (locally advanced disease only); OR b. Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; OR c. Used as continuation (subsequent) therapy if no disease progression after first-line therapy (locally advanced disease only); OR d. 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 v. 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 vi. Used as neoadjuvant therapy; AND

		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 b. Patient has biopsy positive borderline resectable disease; OR vii. Used in combination with gemcitabine and cisplatin; AND a. Patient has metastatic disease; AND b. Patient has ECOG PS 0-1; AND 1.)Used as first-line therapy; OR 2.) Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy" <u>Name change from "Melanoma" to "Cutaneous Melanoma" Initial Criteria</u> Removed "Must be used as a single agent; AND viii. Patient's disease must be unresectable or metastatic; AND a. Patient has uveal melanoma; OR b. Used as second-line or later treatment; AND i. Patient had disease progression or maximum clinical benefit from BRAF targeted therapies" Added "Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; AND ii. Used as subsequent therapy for disease progression; OR iii. Used after maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.) <u>Uveal Melanoma ‡</u> C. Used as a single agent for distant metastatic disease" <u>Removed Bladder Cancer/Urothelial Carcinoma Indication and criteria</u> <u>Uterine Cancer Initial Criteria</u> Removed "Patient has endometrial carcinoma; AND x. Used as one of the following: a. Primary treatment for metastatic or unresectable disease excluding patients with cervical involvement undergoing brachytherapy with or without external beam radiation therapy (EBRT); OR b. Adjuvant treatment, <u>excluding</u> patients with Stage IA disease with adverse risk factors present OR Stage IB disease without adverse risk factors present OR Stage II disease; OR

		c. Used as treatment of local-regional recurrent, progressive or disseminated metastatic disease; AND . 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." 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 iii. Patient has endometroid adenocarcinoma; AND a. Used as primary treatment of disease NOT suitable for primary surgery; AND 1.) Patient has suspected or gross cervical involvement (excluding patients using as chemotherapy alone); OR 2.)Patient has locoregional extrauterine disease; OR 3.)Patient has distant metastases; OR b. Used as primary treatment of disease suitable for primary surgery; AND 1.)Used preoperatively for abdominal/pelvic confined disease; OR 2.)Patient has distant metastases; OR c. Used as adjuvant treatment for stage III-IV disease; OR d. Used for locoregional recurrence or disseminated metastases; OR iv. Patient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/dedifferentiated carcinoma; AND a. Used for locoregional recurrence or disseminated metastases; OR b. Used as additional treatment of metastatic disease that is suitable for primary surgery; OR c. Used as primary treatment of metastatic disease that is NOT suitable for primary Surgery" <u>Name change from "AIDS-related Kaposi Sarcoma" To Kaposi Sarcoma. Initial Criteria</u> Removed "Must be used as subsequent therapy in combination with antiretroviral therapy (ART); AND • Patient has relapsed/refractory advanced, cutaneous, oral, visceral, or nodal disease; AND

		• Patient has disease progression after first-line and alternate first-line treatment" Added: "Used as subsequent 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; AND E. Patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; AND F. Disease has progressed on or not responded to first-line systemic therapy; AND Disease has progressed on alternate first-line systemic therapy" 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.
5. Rizvi NA, Riely GJ, Azzoli CG, et al, "Phase I/II Trial of Weekly Intravenous 130-nm Albumin-Bound Paclitaxel as Initial Chemotherapy in Patients With Stage IV Non-Small-Cell Lung Cancer," *J Clin Oncol*, 2008, 26(4):639-43.
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.