

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

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

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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.

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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

INITIAL APPROVAL 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-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 ‡

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 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. Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) ‡

- 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
 - 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**
 - 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. Pancreatic Adenocarcinoma †

- 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**

- 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. Kaposi Sarcoma ‡

- 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/mm³, 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/m ² OR 125 mg/m ² 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/m ²
NSCLC	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle
	until disease progression or unacceptable toxicity
Cutaneous Melanoma,	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle
Uveal Melanoma, &	until disease progression or unacceptable toxicity
Ovarian Cancer	
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	125 mg/m² days 1, 8, and 15 of a 28-day cycle
Adenocarcinoma &	
Hepatobiliary Cancer	
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	Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle in
Adenocarcinoma	combination with gemcitabine until disease progression or unacceptable
	toxicity
All other indications	260 mg/m² every 21 days
	OR
	100 mg/m ² 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
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C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.123	Malignant neoplasm of upper-inner quadrant of right female breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of territaria breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	
	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
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CS4.8 Malignant neoplasm of turbus uteri CS4.9 Malignant neoplasm of corpus uteri, unspecified CS5.1 Malignant neoplasm of corpus uteri, unspecified CS5.1 Malignant neoplasm of tuterus, part unspecified CS6.1 Malignant neoplasm of left ovary CS6.2 Malignant neoplasm of left ovary CS6.2 Malignant neoplasm of unspecified dovary CS6.2 Malignant neoplasm of unspecified fallopian tube CS7.00 Malignant neoplasm of unspecified fallopian tube CS7.01 Malignant neoplasm of right fallopian tube CS7.02 Malignant neoplasm of right fallopian tube CS7.03 Malignant neoplasm of right broad ligament CS7.11 Malignant neoplasm of right broad ligament CS7.12 Malignant neoplasm of right broad ligament CS7.13 Malignant neoplasm of right broad ligament CS7.14 Malignant neoplasm of right round ligament CS7.15 Malignant neoplasm of right round ligament CS7.16 Malignant neoplasm of right round ligament CS7.17 Malignant neoplasm of parametrium CS7.18 Malignant neoplasm of parametrium CS7.19 Malignant neoplasm of parametrium CS7.10 Malignant neoplasm of parametrium CS7.10 Malignant neoplasm of parametrium CS7.11 Malignant neoplasm of right round ligament CS7.12 Malignant neoplasm of freir specified female genital organs CS7.10 Malignant neoplasm of overlapping sites of female genital organs CS7.10 Malignant neoplasm of freir specified female genital organs CS7.10 Malignant neoplasm of freir renal pelvis CS7.10 Malignant neoplasm of right ureter CS7.10 Malignant neoplasm of right ureter CS7.10 Malignant neoplasm of right ureter CS7.11 Malignant neoplasm of right ureter CS7.12 Malignant neoplasm of specified ureter CS7.13 Malignant neoplasm of specified renal pelvis CS7.14 Malignant neoplasm of right ureter CS7.15 Malignant neoplasm of right ureter CS7.16 Malignant neoplasm of right ureter CS7.17 Malignant neoplasm of specified ureter CS7.10 Malignant neoplasm of right cliary body CS7.21 Malignant ne				
C54.9 Malignant neoplasm of uterus, part unspecified C55. Malignant neoplasm of right ovary C56.2 Malignant neoplasm of right ovary C56.2 Malignant neoplasm of left ovary C56.9 Malignant neoplasm of unspecified 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 right fallopian tube C57.03 Malignant neoplasm of right fallopian tube C57.10 Malignant neoplasm of right broad ligament C57.11 Malignant neoplasm of right broad ligament C57.12 Malignant neoplasm of right broad ligament C57.13 Malignant neoplasm of right round ligament C57.20 Malignant neoplasm of right round ligament C57.21 Malignant neoplasm of right round ligament C57.22 Malignant neoplasm of right round ligament C57.23 Malignant neoplasm of right round ligament C57.24 Malignant neoplasm of other specified female genital organs C57.3 Malignant neoplasm of other specified female genital organs C57.4 Malignant neoplasm of other specified female genital organs C57.9 Malignant neoplasm of other specified female genital organs C57.9 Malignant neoplasm of right renal pelvis C57.9 Malignant neoplasm of infer neoplasm of prostate C57.9 Malignant neoplasm of infer renal pelvis C56.1 Malignant neoplasm of infer renal pelvis C56.2 Malignant neoplasm of infer renal pelvis C56.3 Malignant neoplasm of left renal pelvis C56.4 Malignant neoplasm of infer renal pelvis C57.0 Malignant neoplasm of left ureter C57.1 Malignant neoplasm of ourspecified ureter C57.2 Malignant neoplasm of unspecified ureter C57.3 Malignant neoplasm of unspecified ureter C57.4 Malignant neoplasm of unspecified ureter C57.5 Malignant neoplasm of unspecified ureter C57.6 Malignant neoplasm of unspecified ureter C57.8 Malignant neoplasm of unspecified ureter C57.9	C54.3	Malignant neoplasm of fundus uteri		
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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 unspecified renal pelvis C65.9 Malignant neoplasm of unspecified renal pelvis C66.1 Malignant neoplasm of right ureter C66.2 Malignant neoplasm of right ureter C66.9 Malignant neoplasm of unspecified ureter C67.0 Malignant neoplasm of unspecified ureter C67.1 Malignant neoplasm of trigone of bladder C67.2 Malignant neoplasm of dome of bladder C67.3 Malignant neoplasm of anterior wall of bladder C67.4 Malignant neoplasm of anterior wall of bladder C67.5 Malignant neoplasm of posterior wall of bladder C67.6 Malignant neoplasm of bladder neck C67.6 Malignant neoplasm of ureteric orifice C67.7 Malignant neoplasm of ureteric orifice C67.9 Malignant neoplasm of verlapping sites of bladder C67.9 Malignant neoplasm of urethra C69.30 Malignant neoplasm of unspecified choroid C69.31 Malignant neoplasm of unspecified choroid C69.32 Malignant neoplasm of unspecified choroid C69.40 Malignant neoplasm of unspecified ciliary body C69.41 Malignant neoplasm of inspecified ciliary body C69.42 Malignant neoplasm of left ciliary body	C57.4	Malignant neoplasm of uterine adnexa, unspecified		
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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 voerlapping sites of bladder C67.9 Malignant neoplasm of bladder, unspecified C68.0 Malignant neoplasm of unspecified choroid C69.30 Malignant neoplasm of inght choroid C69.31 Malignant neoplasm of left choroid C69.40 Malignant neoplasm of inght ciliary body C69.41 Malignant neoplasm of left ciliary body C69.42 Malignant neoplasm of left ciliary body	C65.1	Malignant neoplasm of right renal pelvis		
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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 left choroid C69.32 Malignant neoplasm of left choroid C69.40 Malignant neoplasm of unspecified ciliary body C69.41 Malignant neoplasm of left ciliary body C69.42 Malignant neoplasm of left ciliary body	C66.1	Malignant neoplasm of right ureter		
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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 urspecified 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	C66.9	Malignant neoplasm of unspecified ureter		
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	C67.0	Malignant neoplasm of trigone of bladder		
C67.4 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 left ciliary body C69.42 Malignant neoplasm of left ciliary body	C67.1	Malignant neoplasm of dome 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	C67.2	Malignant neoplasm of lateral 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	C67.3	Malignant neoplasm of anterior wall of bladder		
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	C67.4	Malignant neoplasm of posterior wall of bladder		
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	C67.5	Malignant neoplasm of bladder neck		
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	C67.6	Malignant neoplasm of ureteric orifice		
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	C67.7	Malignant neoplasm of urachus		
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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	C68.0	Malignant neoplasm of urethra		
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	C69.30	Malignant neoplasm of unspecified choroid		
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C69.41 Malignant neoplasm of right ciliary body C69.42 Malignant neoplasm of left ciliary body	C69.32	Malignant neoplasm of left choroid		
C69.42 Malignant neoplasm of left ciliary body	C69.40	Malignant neoplasm of unspecified ciliary body		
	C69.41	Malignant neoplasm of right ciliary body		
C69.60 Malignant neoplasm of unspecified orbit	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 &	8/14/2023	Annual Review:
ConnectiCare		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
- Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis;
- iv. Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; OR
- 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"

Non-small cell lung cancer Initial Criteria

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
 - Patient does not have locoregional recurrence without evidence of disseminated disease; AND
 - 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 (\geq 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"

Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) Initial Criteria
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

- 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
 - 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
- 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"

Pancreatic Adenocarcinoma Initial Criteria:

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
 - Patient's disease is resectable with high-risk features or borderline resectable; AND
 - Used for neoadjuvant treatment"

Added "Used as first-line therapy; OR

- 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
- 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
 - 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"

Name change from "Melanoma" to "Cutaneous Melanoma" Initial Criteria

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
 - 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.)

Uveal Melanoma ‡

C. Used as a single agent for distant metastatic disease"

Removed Bladder Cancer/Urothelial Carcinoma Indication and criteria
Uterine Cancer Initial Criteria

Removed "Patient has endometrial carcinoma; AND

- Used as one of the following:
 - Primary treatment for metastatic or unresectable disease excluding patients with cervical involvement undergoing brachytherapy with or without external beam radiation therapy (EBRT); OR
 - 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

 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
 - 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"

Name change from "AIDS-related Kaposi Sarcoma" To Kaposi Sarcoma. Initial Criteria

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

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