



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

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Abraxane 100 mg powder for injection SDV: 9 vials per 21 day supply

B. Max Units (per dose and over time) [Medical Benefit]:

All indications

- 900 billable units per 21 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

Breast cancer †

- Patient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy; **AND**
- Previous chemotherapy included an anthracycline
-OR -‡
- Patient's disease is recurrent or metastatic; **AND**
 - Used as a single agent therapy for disease that is HER2-negative; **AND**
 - Disease is hormone receptor negative; **OR**
 - Disease is hormone receptor positive and patient is refractory to endocrine therapy or has a visceral crisis; **OR**
 - Used in combination with trastuzumab (in patients who were previously treated with trastuzumab) for disease that is HER2-positive; **AND**

- Disease is hormone receptor negative; **OR**
- Disease is hormone receptor positive and used with or without endocrine therapy

-OR-†

- Used as preferred therapy in combination with atezolizumab for PD-L1 positive triple negative recurrent or stage IV (M1) disease

-OR-†

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

Non-small cell lung cancer †

- 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**
 - Recurrent, advanced or metastatic disease in patients who do not have locoregional recurrence or symptomatic local disease without evidence of disseminated disease; **AND**
 - Used as a single agent in patients with a performance status (PS) score of 2 **OR** in combination with carboplatin with a PS score of ≤ 2 **OR** in combination with pembrolizumab **AND** carboplatin or cisplatin for squamous cell histology with a PS score of 0-1; **AND**
 - Patients are genomic tumor aberration (e.g., EGFR, ALK, ROS1, BRAF and PD-L1) negative or unknown **OR** BRAF V600E-mutation positive; **OR**
 - Used in combination with pembrolizumab **AND** carboplatin or cisplatin in patients with a PS score of ≤ 2 and squamous cell carcinoma for PD-L1 expression positive ($\geq 1\%$) tumors that are genomic tumor aberration EGFR and ALK negative or unknown; **OR**
- Used as subsequent therapy for:
 - Recurrent, advanced or metastatic disease in patients who do not have locoregional recurrence or symptomatic local disease without evidence of disseminated disease; **AND**
 - Used as a single agent in patients with a performance status (PS) score of 2 **OR** in combination with carboplatin with a PS score of ≤ 2 **OR** in combination with pembrolizumab **AND** carboplatin or cisplatin for squamous cell histology with a PS score of 0-1; **AND**
 - Patients are genomic tumor aberration (e.g., EGFR, ALK, and ROS1) positive and received targeted therapies for those aberrations; **OR**
 - Patients are BRAF V600E-mutation positive; **OR**
 - Patients have PD-L1 expression-positive ($\geq 1\%$) tumors and are EGFR, ALK negative or unknown with no prior platinum-doublet chemotherapy; **OR**

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

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

- Patient's disease is recurrent or persistent; **AND**
- Patient is not experiencing an immediate biochemical relapse; **AND**
 - Must be used as a single agent; **OR**
 - Used in combination with carboplatin if platinum-sensitive with confirmed taxane hypersensitivity

Pancreatic Adenocarcinoma †

- Must be used in combination with gemcitabine; **AND**
 - Patient's disease is locally advanced or metastatic; **AND**
 - Patient has good performance status (defined as an ECOG PS ≤ 2); **AND**
 - Used as first-line or induction therapy; **OR**
 - Used as second-line therapy after progression with a fluoropyrimidine-based therapy; **OR**
 - Patient's disease is recurrent; **AND**
 - Used as second-line therapy
 - Patient's disease is resectable with high-risk features (i.e., very highly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain) or borderline resectable; **AND**
 - Used for neoadjuvant treatment

Melanoma ‡

- Must be used as a single agent; **AND**
- Patient's disease must be unresectable or metastatic; **AND**
 - Patient has uveal melanoma; **OR**
 - Used as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapies

Bladder Cancer/Urothelial Carcinoma ‡

- Must be used as a single agent; **AND**
- Must be used subsequently following prior treatment with a systemic therapy (i.e., platinum, checkpoint inhibitor, or other recommended regimen); **AND**
- Patient has a diagnosis of one the following:
 - Locally advanced or metastatic disease; **OR**
 - Disease recurrence post-cystectomy; **OR**
 - Metastatic Upper GU tract tumors; **OR**
 - Metastatic Urothelial Carcinoma of the Prostate; **OR**

- Recurrent or metastatic Primary Carcinoma of the Urethra; **AND**
 - Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes

Uterine Cancer ‡

- Used as single agent therapy; **AND**
- Patient has endometrial carcinoma; **AND**
 - Used as primary treatment for one of the following:
 - Metastatic disease; **OR**
 - Unresectable disease excluding patients using chemotherapy alone for disease not suitable for primary surgery with suspected or gross cervical involvement; **OR**
 - Used preoperatively for patients with locally confined disease that is suitable for primary surgery; **OR**
 - Adjuvant treatment, excluding patients with Stage II disease and histologic grade 3 tumors; **OR**
 - Used as treatment of local-regional recurrent, progressive or disseminated metastatic disease; **OR**
 - Used as additional treatment of disease suitable for primary surgery; **AND**
- Patient has tried generic 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.

Hepatobiliary Cancer (Intrahepatic/Extrahepatic Cholangiocarcinoma) ‡

- Must be used in combination with gemcitabine; **AND**
- Used as primary treatment for unresectable or metastatic disease

AIDS-related Kaposi Sarcoma ‡

- 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 had disease progression after first-line and alternate first-line treatment

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

Genomic Aberration Targeted Therapies (not all inclusive) §
Sensitizing EGFR mutation-positive tumors <ul style="list-style-type: none"> – Erlotinib – Afatinib – Gefitinib – Osimertinib – Dacomitinib
ALK rearrangement-positive tumors <ul style="list-style-type: none"> – Crizotinib – Ceritinib – Brigatinib – Alectinib – Lorlatinib

ROS1 rearrangement-positive tumors
– Crizotinib
– Ceritinib
BRAF V600E-mutation positive tumors
– Dabrafenib/Trametinib
<i>NTRK</i> Gene Fusion positive tumors
– Larotrectinib
PD-L1 expression-positive tumors (≥1%)
– Pembrolizumab
– Atezolizumab

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- 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, hepatic impairment, etc.

V. Dosage/Administration

Indication	Dose
Pancreatic Cancer and Hepatobiliary Cancer	125 mg/m ² days 1, 8, and 15 of a 28-day cycle
All other indications	260 mg/m ² every 21 days OR 100 mg/m ² days 1, 8, and 15 of a 21-day cycle

VI. Billing Code/Availability Information

Jcode:

- J9264 – Injection, paclitaxel protein-bound particles, 1 mg; 1 billable unit = 1 mg

NDC:

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

VII. References

1. Abraxane [package insert]. Summit, NJ; Celgene Corporation; August 2018. Accessed May 2019.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium[®]) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2019. 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 May 2019.

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 Metastatic Breast Cancer,” *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. Sahai V, Catalano PJ, Zalupski MM, et al. Nab-Paclitaxel and Gemcitabine as First-line Treatment of Advanced or Metastatic Cholangiocarcinoma: A Phase 2 Clinical Trial. *JAMA Oncol*. 2018;4(12):1707–1712. doi:10.1001/jamaoncol.2018.3277
7. 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 04/19/2019 with effective date of 05/01/2019. Accessed May 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung

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ICD-10	ICD-10 Description
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
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant 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

ICD-10	ICD-10 Description
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

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ICD-10	ICD-10 Description
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

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ICD-10	ICD-10 Description
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

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ICD-10	ICD-10 Description
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
D09.0	Carcinoma in situ of bladder
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 other urinary tract organ

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52450
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52450&bc=gAAAAAAAAAAAAAA==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC