Abraxane (paclitaxel, protein-bound)

Override	Approval Duration
Prior Authorization	1 year

Medication
Abraxane (paclitaxel, protein-bound)

APPROVAL CRITERIA

Requests for Abraxane (paclitaxel, protein-bound) may be approved for the treatment of any of the following indications:

I. Relapsed or metastatic breast cancer when the following criteria are met (Label, NCCN 2A):
   A. Used as a single agent; **AND**
   B. Used in a single line of therapy

OR

II. Metastatic or unresectable locally advanced breast cancer when the following criteria are met (NCCN 1):
   A. Individual has triple-negative breast cancer, defined as lack of estrogen- and progesterone-receptor expression and no overexpression of HER2; **AND**
   B. Individual is using in combination with pembrolizumab;

OR

III. Treatment of any breast cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

IV. Malignant Melanoma when the following criteria are met (NCCN 2A);
   A. Used as:
      1. A single agent; **OR**
      2. In combination with carboplatin;

   AND
   B. Individual is using as second line or subsequent therapy; **AND**
   C. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 (Kottschade 2011);

OR

V. Treatment of recurrent, locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) when the following criteria are met (Label):
   A. Used as first-line therapy; **AND**
   B. Given in combination with carboplatin; **AND**
   C. Individual has an ECOG performance status of 0-2 (NCCN 2A);

OR

VI. Treatment of recurrent, advanced, or metastatic NSCLC when the following criteria are met (NCCN 2A):

A. Used as a single agent for first progression after initial systemic therapy (if not already given); **AND**
B. Individual has an ECOG performance status of 0-2;

VII. Treatment of recurrent, advanced or metastatic squamous NSCLC when all of the following criteria are met (NCCN 1, NCCN 2A):
A. Used as first-line therapy; **AND**
B. Given in combination with carboplatin and pembrolizumab; **AND**
C. Individual has a current ECOG performance status of 0-2;

OR

VIII. Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 2A):
A. Used as first-line therapy; **AND**
B. Given in combination with atezolizumab and carboplatin; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

IX. Treatment of recurrent, advanced, or metastatic nonsquamous NSCLC when the following criteria are met (NCCN 1, 2A):
A. Used as subsequent therapy after failure of kinase inhibitor targeted agent; **AND**
B. Given in combination with carboplatin and atezolizumab; **AND**
C. Individual has an ECOG performance status of 0-2;

OR

X. Treatment of recurrent, advanced, or metastatic squamous NSCLC when the following criteria are met (NCCN 2A):
A. Used as first line therapy; **AND**
B. Individual has no sensitizing epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genetic tumor aberrations; **AND**
C. Individual is using in combination with tremelimumab-actl, durvalumab, and carboplatin; **AND**
D. Individual has a PD-L1 expression ≥ 1% and less than or equal to 49%; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
F. Individual has an ECOG performance status of 0-2;

OR

XI. Treatment of NSCLC in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XII. Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) when the following criteria are met (NCCN 1, 2A):
A. Treatment of persistent or recurrent ovarian cancer when used as a single agent (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer); **OR**
B. Treatment of persistent or recurrent ovarian cancer when used with carboplatin (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity;

OR

XIII. Locally advanced or metastatic adenocarcinoma of the pancreas when the following criteria are met (Label, NCCN 1, 2A):
   A. Used as first-line therapy or as continuation (maintenance therapy); **AND**
   B. Given in combination in one of the following ways:
      1. With gemcitabine as a single-line of therapy; **OR**
      2. With gemcitabine and cisplatin;

OR

XIV. Recurrent, metastatic, or high-risk endometrial cancer in an individual with confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XV. Solid tumors where treatment with a taxane is medically appropriate and the individual has confirmed taxane (that is, solvent-based paclitaxel or docetaxel) hypersensitivity (NCCN 2A);

OR

XVI. Advanced or metastatic small bowel adenocarcinoma, when the following criteria are met (NCCN 2A):
   A. Treatment of advanced or metastatic disease; **AND**
   B. Given in combination with gemcitabine;

OR

XVII. Ampullary adenocarcinoma, when the following criteria are met (NCCN 2A):
   A. Treatment in pancreatobiliary and mixed type disease; **AND**
   B. Given in combination with gemcitabine; **AND**
   C. Individual has an ECOG performance status of 0-2.

Abraxane (paclitaxel, protein-bound) may not be approved for the following:

I. Individual has baseline neutrophil count of less than 1,500 cells/mm^3 prior to initiation of Abraxane; **OR**
II. When the above criteria are not met and for all other indications.

Note:
Abraxane label includes a black box warning restricting use in patients with baseline neutrophil counts of less than 1,500 cells/mm^3, and frequent peripheral blood cell counts should be performed to monitor for bone marrow suppression.

Key References:

1. Abu-Khalaf MM, Baumgart MA, Gettinger SN, et al. Phase 1b study of the mammalian target of rapamycin inhibitor sirolimus in combination with nanoparticle albumin-bound paclitaxel in patients with advanced solid tumors. Cancer. 2015; 121(11):1817-1826.
2. Adkins D, Ley J, Michel L, et al. Nab-paclitaxel, cisplatin, and 5-fluorouracil followed by concurrent cisplatin and radiation for head and neck squamous cell carcinoma. Oral Oncol. 2016; 61:1-7.
3. Adkins D, Ley J, Trinkaus K, et al. A phase 2 trial of induction nab-paclitaxel and cetuximab given with cisplatin and 5-fluorouracil followed by concurrent cisplatin and radiation for locally advanced squamous cell carcinoma of the head and neck. Cancer. 2013; 119(4):766-773.
4. Alberts DS, Blessing JA, Landrum LM, et al. Phase II trial of nab-paclitaxel in the treatment of recurrent or persistent advanced cervix cancer: a gynecologic oncology group study. Gynecol Oncol. 2012; 127(3):451-455.
5. Aldrich JD, Raghav KPS, Varadhachary GR, et al. Retrospective analysis of taxane-based therapy in small bowel adenocarcinoma. *Oncologist*. 2019;24:e384-6.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
7. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
8. Damascelli B, Patelli G, Ticha V, et al. Feasibility and efficacy of percutaneous transcatheter intraarterial chemotherapy with paclitaxel in albumin nanoparticles for advanced squamous-cell carcinoma of the oral cavity, oropharynx, and hypopharynx. J Vasc Interv Radiol. 2007; 18(11):1395-1403.
9. Demeure MJ, Stephan E, Sinari S, et al. Preclinical investigation of nanoparticle albumin-bound paclitaxel as a potential treatment for adrenocortical cancer. Ann Surg. 2012; 255(1):140-146.
10. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
11. Fan Y, Jiang Y, Zhou X, et al. Phase II study of neoadjuvant therapy with nab-paclitaxel and cisplatin followed by surgery in patients with locally advanced esophageal squamous cell carcinoma. Oncotarget. 2016; 7(31):50624-50634.
12. Fortino S, Santoro M, Iuliano E, et.al. Treatment of Kaposi's Sarcoma (KS) with nab-paclitaxel. Ann Oncol 2016:27:suppl_4: iv124.
13. Grilley-Olson JE, Keedy VL, Sandler A, et al. A randomized phase II study of carboplatin with weekly or every-3-week nanoparticle albumin-bound paclitaxel (Abraxane) in patients with extensive-stage small cell lung cancer. Oncologist. 2015; 20(2):105-106.
14. Hirata T, Yonemori K, Ando M, et al. Efficacy of taxane regimens in patients with metastatic angiosarcoma. Eur J Dermatol. 2011; 21(4):539-545.
15. Huang Y, Liang W, Yang Y, et al. Phase I/II dose-finding study of nanoparticle albumin-bound paclitaxel (nab®-paclitaxel) plus cisplatin as treatment for metastatic nasopharyngeal carcinoma. BMC Cancer. 2016; 16:464.
16. Koizumi W, Morita S, Sakata Y. A randomized Phase III trial of weekly or 3-weekly doses of nab-paclitaxel versus weekly doses of Cremophor-based paclitaxel in patients with previously treated advanced gastric cancer (ABSOLUTE Trial). Jpn J Clin Oncol. 2015; 45(3):303-306.
17. Kottschade LA, Suman VJ, Amatruda T 3rd, et al. A phase II trial of nab-paclitaxel (ABI-007) and carboplatin in patients with unresectable stage IV melanoma: a North Central Cancer Treatment Group Study, N057E(1). Cancer. 2011; 117(8):1704-1710.
18. Ko YJ, Canil CM, Mukherjee SD, et al. Nanoparticle albumin-bound paclitaxel for second-line treatment of metastatic urothelial carcinoma: a single group, multicentre, phase 2 study. Lancet Oncol. 2013; 14(8):769-776.
19. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
20. Li Y, Zeng J, Huang M, et al. A phase 2 study of nanoparticle albumin-bound paclitaxel plus nedaplatin for patients with advanced, recurrent, or metastatic cervical carcinoma. Cancer. 2017; 123(3):420-425.
21. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 29, 2022.
    a. Ampullary adenocarcinoma. V2.2022. Revised December 6, 2022.
    b. Breast cancer. V4.2022. Revised June 21, 2022
    c. Cervical Cancer V1.2023. Revised December 23, 2022.
    d. Cutaneous Melanoma. V1.2023. Revised December 22, 2022.
    e. Hepatobiliary Cancers. V4.2022. Revised December 9, 2022.
    f. Kaposi Sarcoma. V1.2023. Revised December 20, 2022.
    g. Non-Small cell lung cancer. V1.2023. Revised December 22, 2022.
    h. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V1.2023. Revised December 22, 2022.
    i. Pancreatic Adenocarcinoma. V2.2022. Revised December 6, 2022.
    j. Small Bowel Adenocarcinoma. V2.2022. Revised October 27, 2022.
    k. Uterine Neoplasms. V1.2023. Revised December 22, 2022.
    l. Uveal melanoma. V2.2022. Revised April 5, 2022.

22. Overman MJ, Adam L, Raghav K, et al. Phase II study of nab-paclitaxel in refractory small bowel adenocarcinoma and CpG island methylator phenotype (CIMP)-high colorectal cancer. *Ann Oncol.* 2018;29:139-44.
23. 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. Available at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2698042. Accessed December 29, 2022.
24. Shepard DR, Dreicer R, Garcia J, et al. Phase II trial of neoadjuvant nab-paclitaxel in high risk patients with prostate cancer undergoing radical prostatectomy. J Urol. 2009; 181(4):1672-1677; discussion 1677.
25. Shi Y, Qin R, Wang ZK, Dai GH. Nanoparticle albumin-bound paclitaxel combined with cisplatin as the first-line treatment for metastatic esophageal squamous cell carcinoma. Onco Targets Ther. 2013; 6:585-591.
26. Tecentriq® (atezolizumab) [Product Information]. San Francisco: Genentech, Inc. Accessed on December 29, 2022.
27. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019 Jul;20(7):924-937. Epub 2019 May 20.
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