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. Individual has a diagnosis of Breast Cancer; **AND**
  A. Individual is using as a single agent after failure on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy (Label); **AND**
    1. Individual has had previous chemotherapy including an anthracycline unless clinically contraindicated;

OR

  B. Individual has recurrent unresectable or metastatic (stage IV) disease; **AND**
    1. Individual has HER2 negative disease (NCCN 2A): **AND**
      a. Individual is using as a single agent or in combination with carboplatin; **AND**
      b. Disease is hormone receptor-positive and refractory to endocrine therapy or has visceral crisis; **AND**
      c. Using in one of the following ways:
        i. First line therapy if no germline BRCA 1/2 mutation; **OR**
        ii. Second-line therapy if not a candidate for fam trastuzumab deruxtecan-nxki; **OR**
        iii. Third-line and beyond;

OR

    2. Individual has triple negative breast cancer (NCCN 2A); **AND**
      a. Individual has disease with high tumor burden, rapidly progressing disease and visceral crisis; **AND**
      b. Individual is using as a single agent or in combination with carboplatin; **AND**
      c. Using in one of the following ways:
        i. First line therapy if PD-L1 < 10 and no germline BRCA 1/2 mutation; **OR**
        ii. Second-line therapy and beyond;

OR

      d. Individual has PD-L1 positive, triple-negative disease; **AND**
        i. Individual is using in combination with pembrolizumab; **AND**
        ii. Using in one of the following ways:

1. As first line therapy (NCCN 1); **OR**
2. Second and subsequent line of therapy if PD-1/PD-L1 inhibitor has not been previously used (NCCN 2A);

OR

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

OR

II. Individual has a diagnosis of recurrent or metastatic cervical cancer (NCCN 2A); **AND**
   A. Individual is using as second-line or subsequent therapy; **AND**
   B. Individual is using as a single agent;

OR

III. Individual has a diagnosis of Malignant Melanoma (NCCN 2A);
   A. Individual is using 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

IV. Individual has a diagnosis of recurrent, locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
   A. Individual is using as first-line therapy; **AND**
   B. Individual is using in combination with carboplatin; **AND**
   C. Individual has an ECOG performance status of 0-2 (NCCN 2A);

OR

V. Individual has a diagnosis of recurrent, advanced, or metastatic NSCLC; **AND**
   A. Individual is using 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;

OR

VI. Individual has a diagnosis of recurrent, advanced or metastatic squamous NSCLC (NCCN 1, 2A); **AND**
   A. Individual is using as first-line therapy; **AND**
   B. Individual is using in combination with carboplatin and pembrolizumab; **AND**
   C. Individual has a current ECOG performance status of 0-2;

OR

VII. Individual has a diagnosis of recurrent, advanced, or metastatic nonsquamous NSCLC (NCCN 2A); **AND**
   A. Individual is using as first-line therapy; **AND**
   B. Individual is using in combination with atezolizumab and carboplatin; **AND**
   C. Individual has an ECOG performance status of 0-2;

OR

VIII. Individual has a diagnosis of recurrent, advanced, or metastatic nonsquamous NSCLC (NCCN 1, 2A); **AND**
- A. Individual is using as subsequent therapy after failure of kinase inhibitor targeted agent; **AND**
- B. Individual is using in combination with carboplatin and atezolizumab; **AND**
- C. Individual has an ECOG performance status of 0-2;

OR

IX. Individual has a diagnosis of recurrent, advanced, or metastatic squamous NSCLC - (NCCN 2A); **AND**
- A. Individual is using 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

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

OR

XI. Individual has a diagnosis of Ovarian Cancer (Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer) (NCCN 1, 2A); **AND**
- A. Individual is using for the 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. Individual is using for the 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

XII. Individual has a diagnosis of metastatic adenocarcinoma of the pancreas (Label, NCCN 1, 2A); **AND**
- A. Individual is using as first-line therapy; **AND**
- B. Individual is using in combination in one of the following ways:
  1. With gemcitabine as a single-line of therapy; **OR**
  2. With gemcitabine and cisplatin;

OR

XIII. Individual has a diagnosis of locally advanced adenocarcinoma of the pancreas (NCCN 2A); **AND**
- A. Individual is using as first-line therapy or as continuation (maintenance therapy); **AND**

B. Individual is using in combination with gemcitabine as a single-line of therapy;

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. Individual has a diagnosis of small bowel adenocarcinoma (NCCN 2A); **AND**
- A. Individual has advanced or metastatic disease; **AND**
- B. Individual is using as a single agent or in combination with gemcitabine;

OR

XVII. Individual has a diagnosis of Ampullary adenocarcinoma (NCCN 2A); **AND**
- A. Individual is using in pancreatobiliary and mixed type disease; **AND**
- B. Individual is using in combination with gemcitabine; **AND**
- C. Individual has an ECOG performance status of 0-2;

OR

XVIII. Individual has a diagnosis of Biliary Tract Cancer (NCCN 2A); **AND**
- A. Individual is using in unresectable or resected gross residual disease **OR** metastatic disease; **AND**
- B. Individual is using in combination with gemcitabine.

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.: 2024. 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.; 202;4 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™. © 2024 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. V1.2024. Revised December 13, 2023.
    b. Breast cancer. V5.2023. Revised December 5, 2023.
    c. Biliary Tract Cancers. V3.2023. Revised November 8, 2023.
    d. Cervical Cancer V1.2024. Revised September 20, 2023.
    e. Cutaneous Melanoma. V3.2023. Revised October 27, 2023.
    f. Kaposi Sarcoma. V1.2024. Revised November 7, 2023.
    g. Non-Small cell lung cancer. V1.2024. Revised December 21, 2023
    h. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V2.2023. Revised June 2, 2023
    i. Pancreatic Adenocarcinoma. V1.2024. Revised December 13, 2023.
    j. Small Bowel Adenocarcinoma. V1.2024. Revised December 20, 2023.
    k. Uterine Neoplasms. V1.2024. Revised September 20, 2023
    l. Uveal melanoma. V1.2023. Revised May 4, 2023

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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.