New Century Health

Drug Policy:

Abraxane™ (nab-paclitaxel)

POLICY NUMBER UM ONC_1179	SUBJECT Abraxane™ (nab-paclitaxel)		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 09/09/11, 12/12/12, 01/02/13, 01/08/14, 06/10/15, 06/08/16, 11/08/16, 02/06/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 04/08/20, 06/10/20, 05/12/21, 09/08/21, 11/15/21, 04/13/22, 05/11/22, 11/09/22, 01/11/23, 02/08/23, 03/08/23, 05/10/23	APPROVAL DATE May 10, 2023	EFFECTIVE DATE May 26, 2023	COMMITTEE APPROVAL DATES 09/09/11, 12/12/12, 01/02/13, 01/08/14, 06/10/15, 06/08/16, 11/08/16, 02/06/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 04/08/20, 06/10/20, 05/12/21, 09/08/21, 11/15/21, 04/13/22, 05/11/22, 11/09/22, 01/11/23, 02/08/23, 03/08/23, 05/10/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Abraxane (nab-paclitaxel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Breast Cancer

1. NOTE: Abraxane and Abraxane-based regimens, [e.g., Abraxane (nab-paclitaxel) +/- Keytruda (pembrolizumab)] are not supported by NCH Policy for adjuvant therapy of stages I-III breast cancer OR the treatment of recurrent unresectable or metastatic breast cancer. This policy position is based on the lack of Level 1 evidence to show superior outcomes with Abraxane (albumin-bound paclitaxel) compared to Taxol (paclitaxel). Also, for metastatic breast cancer the results of the KEYNOTE-355 trial showed comparable outcomes with the above combination compared to [Taxol(paclitaxel) + Keytruda (pembrolizumab)] and [Gemcitabine + Carboplatin + Keytruda (pembrolizumab)]; see reference below. Abraxane (nab-paclitaxel) would be supported per NCH Policy if the member has a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel). Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.

C. Cervical Cancer, Endometrial Cancer, and Ovarian Cancer

1. NOTE: Abraxane (albumin-bound paclitaxel) is not supported by NCH Policy for the treatment of cervical cancer, endometrial cancer, and ovarian cancer. This policy position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Abraxane (albumin-bound paclitaxel) compared to Taxol (paclitaxel) or Taxotere (docetaxel). Abraxane (nab-paclitaxel) would be supported per NCH Policy if the member has a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel). Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.

D. Melanoma

1. NOTE: Abraxane (albumin-bound paclitaxel) is not supported by NCH Policy for the treatment unresectable/metastatic cutaneous melanoma. This policy position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Abraxane (albumin-bound paclitaxel) compared to the NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.

E. Non-Small Cell Lung Cancer (NSCLC)

1. NOTE: Abraxane (albumin-bound paclitaxel) +/- carboplatin +/- Keytruda (pembrolizumab) (for squamous histology)/atezolizumab (for non-squamous histology) are not supported by NCH Policy for initial or subsequent treatment of NSCLC. This policy position is based on:
    a. The results of the KEYNOTE- 407 trial which showed equivalent Progression Free Survival and Overall Survival with both Abraxane and Taxol (solvent-based paclitaxel). KEYNOTE-407 is referenced below.
    b. Lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with Abraxane-based combinations compared to Taxol (paclitaxel-solvent based) combinations in patients with metastatic Non-Small Cell Lung Cancer.
2. Abraxane (nab-paclitaxel) use in the above setting would be supported by NCH Policy if there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel). Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.

F. Pancreatic Adenocarcinoma

1. Abraxane (nab-paclitaxel) may be used in combination with gemcitabine as neoadjuvant therapy for borderline resectable or locally advanced disease OR

2. Abraxane (nab-paclitaxel) may be used in combination with gemcitabine for first or subsequent line therapy for recurrent/metastatic disease for members who have not received/progressed on prior Abraxane (nab-paclitaxel).

III. EXCLUSION CRITERIA

A. Disease progression while receiving Abraxane (nab-paclitaxel) or an Abraxane containing regimen.

B. Dosing exceeds single dose limit of Abraxane (nab-paclitaxel) 260 mg/m^2 if given every 3 weeks.

C. Investigational use of Abraxane (nab-paclitaxel) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Cortes J, et al. KEYNOTE-355 Clinical Trial. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-

negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. Lancet. 2020 Dec 5;396(10265):1817-1828.

B. Schmid P, et al. IMpassion130 Trial. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. N Engl J Med. 2018 Nov 29;379(22):2108-2121.

C. Paz-Ares L, et al. A Randomized, Placebo-Controlled Trial of Pembrolizumab Plus Chemotherapy in Patients With Metastatic Squamous NSCLC: Protocol-Specified Final Analysis of KEYNOTE-407. J Thorac Oncol. 2020 Oct;15(10):1657-1669.

D. Paz-Ares L, et al. KEYNOTE-407 Trial. Pembrolizumab plus Chemotherapy for Squamous Non-Small-Cell Lung Cancer. N Engl J Med. 2018 Nov 22;379(21):2040-2051.

E. Von Hoff DD, et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. N Engl J Med. 2013 Oct 31;369(18):1691-703.

F. Sohal DPS, et al. Metastatic Pancreatic Cancer: ASCO Guideline Update. J Clin Oncol. 2020 Aug 5:JCO2001364.

G. Abraxane prescribing information. Abraxis BioScience, LLC Bridgewater, NJ 2022.

H. Clinical Pharmacology Elsevier Gold Standard 2023.

I. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

L. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

M. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

N. NCQA UM 2023 Standards and Elements.