**Drug Policy:**

**Abraxane™ (nab-paclitaxel)**

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**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

**APPROVAL DATE**
May 12, 2021

**EFFECTIVE DATE**
May 28, 2021

**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

**PRIMARY BUSINESS OWNER:** UM

**COMMITTEE/BOARD APPROVAL**
Utilization Management Committee

**URAC STANDARDS**
HUM 1

**NCQA STANDARDS**
UM 2

**ADDITIONAL AREAS OF IMPACT**

**CMS REQUIREMENTS**

**STATE/FEDERAL REQUIREMENTS**

**APPLICABLE LINES OF BUSINESS**
Commercial, Exchange, Medicaid

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**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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. NOTE: For all cancer types in which a taxane (Taxol, Taxotere, Abraxane) is indicated-except pancreas adenocarcinoma and metastatic/recurrent triple negative breast carcinoma-NCH Policy & NCH Pathway require the use of solvent-based Taxol (paclitaxel) or Taxotere (docetaxel) over the use of Abraxane (nab-paclitaxel), unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).

C. Breast Cancer
   1. For recurrent/metastatic triple negative breast cancer that is PD-L1 positive (CPS- Combined Positive Score of 1% or higher), Abraxane (nab-paclitaxel) may be used in combination with Tecentriq (atezolizumab) in the first line setting OR in the second line/subsequent line setting if the member has not received the above regimen previously and there is no history of progression on another Immune Checkpoint Inhibitor (e.g., Keytruda).

D. Pancreatic Adenocarcinoma
   1. Abraxane (nab-paclitaxel) may be used in combination with gemcitabine for 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 the above regimen for metastatic disease).

E. Non-Small Cell Lung Cancer (NSCLC)
   1. In the first line setting for metastatic, squamous, Non-Small Cell Lung Cancer, Taxol (paclitaxel) is preferred over Abraxane (nab-paclitaxel). The above recommendation is based on results of KEYNOTE-407 trial which showed no difference in outcomes between the use of Taxol (paclitaxel) and Abraxane (nab-paclitaxel).
   2. For first & subsequent line settings, for both metastatic and non-metastatic Non-Small Cell Lung Cancer, the use of solvent based Taxol (paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Abraxane (nab-paclitaxel) compared to Taxol (paclitaxel) or Taxotere (docetaxel).
   3. Please refer to NCH Pathway for the recommended regimens/agents for the most current recommended regimens/agents for Non-Small Cell Lung Cancer.

III. EXCLUSION CRITERIA
   A. Disease progression while receiving Abraxane or an Abraxane containing regimen.
   B. Dosing exceeds single dose limit of Abraxane (nab-paclitaxel) 260 mg/m² if given every 3 weeks.
   C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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


