

<b>POLICY NUMBER</b> UM ONC_1179	<b>SUBJECT</b> Abraxane™ (nab-paclitaxel)	<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 2</b>
<b>DATES COMMITTEE REVIEWED</b> 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	<b>APPROVAL DATE</b> June 10, 2020	<b>EFFECTIVE DATE</b> June 26, 2020	<b>COMMITTEE APPROVAL DATES</b> (latest version listed last) 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
<b>PRIMARY BUSINESS OWNER: UM</b> <b>APPROVED BY:</b> Dr. Andrew Hertler		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee	
<b>URAC STANDARDS</b> HUM 1		<b>NCQA STANDARDS</b> UM 2	<b>ADDITIONAL AREAS OF IMPACT</b>
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>	<b>APPLICABLE LINES OF BUSINESS</b> All	

## 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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

### 1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- 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**
- 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**
- 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**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

- 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).**

### 3. Breast Cancer



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- a. For recurrent/metastatic triple negative breast cancer that is PD-L1 positive (CPS-Combined Positive Score in the tumor tissue is 1% or higher) **AND**
- b. Abraxane (nab-paclitaxel) is being used in combination with Atezolizumab.

#### **4. Pancreatic Adenocarcinoma**

- c. Abraxane is being used in combination with gemcitabine for neoadjuvant therapy for borderline resectable or locally advanced disease **OR**
- d. Abraxane is being used in combination with gemcitabine for first or subsequent line of therapy for recurrent/metastatic disease (for members who have not received the above regimen for metastatic disease).

#### **5. Non-Small Cell Lung Cancer (NSCLC)**

- a. **Per NCH Policy & NCH Pathway the use of solvent based Taxol ( paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) for NSCLC, unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).**
- b. **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**

- 1. Off-label indications for Abraxane (nab-paclitaxel) in ovarian cancer, metastatic melanoma, urothelial carcinoma, and endometrial carcinoma.
- 2. Disease progression while receiving Abraxane or an Abraxane containing regimen.
- 3. Dosing exceeds single dose limit of Abraxane (nab-paclitaxel) 260 mg/m<sup>2</sup> if given every 3 weeks.
- 4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

### **IV. MEDICATION MANAGEMENT**

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

### **V. APPROVAL AUTHORITY**

- 1. Review – Utilization management Department
- 2. Final Approval – Utilization Management Committee

### **VI. ATTACHMENTS**

None

### **VII. REFERENCES**

- 1. Abraxane prescribing information. Abraxis BioScience, LLC Bridgewater, NJ. 2020.
- 2. Clinical Pharmacology Elsevier Gold Standard. 2020.
- 3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- 4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- 5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.