Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PHAR.176	**Effective Date: 01/2018** **Revision Date: 04/15/2020**
Policy Name: Paclitaxel, protein-bound (Abraxane)	

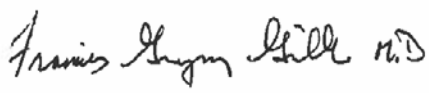
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Paclitaxel, Protein-Bound (Abraxane)

Reference Number: PA.CP.PHAR.176
Effective Date: 01/18
Last Review Date: 04/2020 Revision Log

Coding Implications

Description
Protein-bound paclitaxel (Abraxane®) is microtubule inhibitor.

FDA approved indication
Abraxane is indicated for the treatment of:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Abraxane is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of breast cancer;
2. Disease is recurrent or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. For triple negative breast cancer (i.e., estrogen, progesterone, and human epidermal growth factor receptor 2 [HER2] negative): Prescribed in combination with Tecentriq®;*
      **Prior authorization is required for Tecentriq*
   b. For non-triple negative breast cancer: Prior therapy* included an anthracycline (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin), unless all are contraindicated;
6. **Prior authorization may be required for prior therapies*;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 260 mg/m^2 every 3 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of non-small cell lung cancer (NSCLC);
2. Medical justification supports inability to use paclitaxel;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 100 mg/m^2 IV on Days 1, 8, and 15 of each 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Adenocarcinoma of the Pancreas (must meet all)**:**
1. Diagnosis of adenocarcinoma of the pancreas;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Abraxane will be used in combination with gemcitabine*;
   **Gemcitabine may require prior authorization*
5. Disease is metastatic, unresectable, or borderline resectable;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 125 mg/m^2 on Days 1, 8 and 15 of each 28-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Additional NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the indications supported by NCCN categories 1 and 2A (a - g):
   a. AIDS-related Kaposi sarcoma;
   b. Bladder cancer;
   c. Cutaneous or uveal melanoma;
   d. Endometrial carcinoma;
   e. Hepatic cholangiocarcinoma;
   f. Relapsed ovarian cancer;
   g. Advanced or metastatic small bowel adenocarcinoma
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Other diagnoses/indications *(including NCCN category I and 2A indications not already listed).*

1. Refer to PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, meets one of the following (a or b):
   a. New dose does not exceed one of the following (i, ii, or iii):
      i. For breast cancer: 260 mg/m^2 IV every 3 weeks;
      ii. For NSCLC: 100 mg/m^2 IV on Days 1, 8, and 15 of each 21-day cycle;
      iii. For adenocarcinoma of the pancreas: 125 mg/m^2 on Days 1, 8 and 15 of each 28-day cycle
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
HER2: human epidermal growth factor receptor 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
anthracyclines (e.g., doxorubicin, pegylated liposomal doxorubicin, epirubicin)	For breast cancer: Refer to prescribing information	Refer to prescribing information
paclitaxel (Taxol®)	For NSCLC: 135 mg/m^2 IV administered over 24 hours followed by cisplatin (75	250 mg/m^2 every 3 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	mg/m^2 IV) every 3 weeks based on clinical status of the patient	
gemcitabine (Gemzar®)	For adenocarcinoma of the pancreas: 1,000 mg/m^2 IV over 30 to 40 minutes on days 1, 8, and 15 preceded by nab-paclitaxel (125 mg/m^2 IV over 30 to 40 minutes on days 1, 8, and 15) every 28 days	1000 mg/m^2 once weekly for up to 7 consecutive weeks
Tecentriq® (atezolizumab)	For breast cancer: 840 mg IV on days 1 and 15	840 mg/2 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): neutrophil counts of < 1,500 cells/mm^3, hypersensitivity
- Boxed warning(s): neutropenia

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Metastatic breast cancer	260 mg/m^2 IV every 3 weeks	260 mg/m^2
Non-small cell lung cancer	100 mg/m^2 IV on days 1, 8, and 15 of each 21-day cycle	260 mg/m^2
Metastatic adenocarcinoma of the pancreas	125 mg/m^2 IV on days 1, 8 and 15 of each 28-day cycle	260 mg/m^2

V. Product Availability

Injectable suspension: lyophilized powder containing 100 mg of paclitaxel formulated as albumin-bound particles in single-use vial for reconstitution.

VI. References

1. Abraxane Prescribing Information. Summit, NJ: Celgene Corporation; December 2019. Available at http://www.abraxane.com/. Accessed February 16, 2020.
2. Paclitaxel, albumin bound. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 16, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 16, 2020.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

The following is a list of procedures codes for which coverage may be provided when billed with a diagnosis code(s) that supports coverage criteria (see list of ICD codes supporting coverage criteria further below).

CPT® /HCPCS Codes	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration; each additional hour (List separately in addition to code for primary procedure)
J9264	Injection, paclitaxel protein-bound particles, 1 mg

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-10-CM Code	Description
C22.1	Intrahepatic bile duct carcinoma
C25.0-C25.9	Malignant neoplasm of pancreas
C34.00-C34.02	Malignant neoplasm of main bronchus
C34.10-C34.12	Malignant neoplasm of upper lobe, bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30-C34.32	Malignant neoplasm of lower lobe, bronchus or lung
C34.80-C34.82	Malignant neoplasm of overlapping sites of bronchus or lung
C34.90-C34.92	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C43.0-C43.8	Melanoma and other malignant neoplasms of skin
C46.0-C46.9	Kaposi's sarcoma
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011-C50.012	Malignant neoplasm of nipple and areola, female breast
C50.021-C50.022	Malignant neoplasm of nipple and areola, male breast
C50.111-C50.112	Malignant neoplasm of central portion of female breast
C50.121-C50.122	Malignant neoplasm of central portion of male breast
C50.211-C50.212	Malignant neoplasm of upper-inner quadrant of female breast
C50.221-C50.222	Malignant neoplasm of upper-inner quadrant of male breast
C50.311-C50.312	Malignant neoplasm of lower-inner quadrant of female breast
C50.321-C50.322	Malignant neoplasm of lower-inner quadrant of male breast
C50.411-C50.412	Malignant neoplasm of upper-outer quadrant of female breast
C50.421-C50.422	Malignant neoplasm of upper-outer quadrant of male breast

ICD-10-CM Code	Description
C50.511-C50.512	Malignant neoplasm of lower-outer quadrant of female breast
C50.521-C50.522	Malignant neoplasm of lower-outer quadrant of male breast
C50.611-C50.612	Malignant neoplasm of axillary tail of female breast
C50.621-C50.622	Malignant neoplasm of axillary tail of male breast
C50.811-C50.812	Malignant neoplasm of overlapping sites of female breast
C50.821-C50.822	Malignant neoplasm of overlapping sites of male breast
C54.1	Malignant neoplasm of endometrium
C56.1-C56.2	Malignant neoplasm of ovary
C57.01-C57.02	Malignant neoplasm of fallopian tube
C57.11-C57.12	Malignant neoplasm of broad ligament
C57.21-C57.22	Malignant neoplasm of round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C65.1 – C65.2	Malignant neoplasm of renal pelvis
C67.0 – C67.9	Malignant neoplasm of bladder
C68.0	Malignant neoplasm of urethra
Z85.05	Personal history of malignant neoplasm of liver
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs
Z85.51	Personal history of malignant neoplasm of bladder
Z85.53	Personal history of renal pelvis
Z85.820	Personal history of malignant melanoma of skin

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age; NCCN category 2B indication for cervical cancer removed; for all indications: removed requirements to check for contraindications per safety guidance, summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.07.18	
2Q 2019 annual review: added NCCN 2A off-label uses: endometrial carcinoma and hepatic cholangiocarcinoma; references reviewed and updated.	04/19	
2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated.	04/2020	