Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 36.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Abraxane (paclitaxel protein bound particles)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Abraxane (paclitaxel protein bound particles)

II. Purpose/Objective:
To provide a policy of coverage regarding Abraxane (paclitaxel protein bound particles)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Abraxane (paclitaxel protein bound particles) is a formulation of paclitaxel that is free of the solvent polyoxyethylated castor oil (Cremophor), which is thought to be the cause of the hypersensitivity reactions frequently encountered with standard paclitaxel.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Abraxane (paclitaxel protein bound) will be considered medically necessary for the commercial, exchange, CHIP and Medicaid lines of business when the following criteria are met:

1. **Breast Cancer when the following criteria is met:**
    - Treatment of breast cancer after failure of combination chemotherapy which should have included an anthracycline (unless clinically contraindicated) for metastatic disease or relapse within 6 months of adjuvant chemotherapy **AND**
    - Physician provided documentation of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy **AND**
    - Physician provided documentation of prior therapy with an anthracycline, or documentation of clinical contraindication to its use **AND**
    - Physician provided documentation of intolerance to or contraindication to standard paclitaxel therapy **AND**
    - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
    - If a brand drug is being requested when a therapeutically equivalent generic drug exists:
        - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
        - Medical record documentation of an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s) **AND**
    - Prescribed by a hematologist/oncologist **OR**
2. **Locally advanced or metastatic non-small cell lung cancer (NSCLC) when the following criteria is met:**
    - First–line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), in combination with carboplatin in insured individuals who are not candidates for curative surgery or radiation therapy **AND**
    - Physician provided documentation of intolerance to or contraindication to standard paclitaxel therapy **AND**
    - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
    - If a brand drug is being requested when a therapeutically equivalent generic drug exists:
        - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
        - Medical record documentation of an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s) **AND**
    - Prescribed by a hematologist/oncologist **OR**
3. **Metastatic adenocarcinoma of the pancreas when the following criteria is met:**
    - First-line treatment of metastatic adenocarcinoma of the pancreas when used in combination with gemcitabine with a good performance status (ECOG score 0-2 or Karnofsky score greater than or equal to 60%) **AND**
    - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
    - If a brand drug is being requested when a therapeutically equivalent generic drug exists:

- Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
- Medical record documentation of an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s) **AND**

- Prescribed by a hematologist/oncologist

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Abraxane (paclitaxel protein bound) will be considered medically necessary for the Medicare line of business when the following criteria are met:

1. **Breast Cancer when the following criteria is met:**
   - Treatment of breast cancer after failure of combination chemotherapy which should have included an anthracycline (unless clinically contraindicated) for metastatic disease or relapse within 6 months of adjuvant chemotherapy **AND**
   - Physician provided documentation of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy **AND**
   - Physician provided documentation of prior therapy with an anthracycline, or documentation of clinical contraindication to its use **AND**
   - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
   - Prescribed by a hematologist/oncologist **OR**
2. **Locally advanced or metastatic non-small cell lung cancer (NSCLC) when the following criteria is met:**
   - First–line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), in combination with carboplatin in insured individuals who are not candidates for curative surgery or radiation therapy **AND**
   - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
   - Prescribed by a hematologist/oncologist **OR**
3. **Metastatic adenocarcinoma of the pancreas when the following criteria is met:**
   - First-line treatment of metastatic adenocarcinoma of the pancreas when used in combination with gemcitabine with a good performance status (ECOG score 0-2 or Karnofsky score greater than or equal to 60%) **AND**
   - Medical record documentation that the member has a baseline neutrophil count greater than or equal to 1,500 cells/mm^3 **AND**
   - Prescribed by a hematologist/oncologist

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Abraxane [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/9/05

Revised: 12/5/06, 1/13; 08/14, 1/18/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 2/16/23 (neutrophil count per DHS), 12/31/23 (references added), 1/9/24 (added generic drug language), 1/7/25 (LOB table, taglines)

Reviewed: 12/07, 02/09, 5/10; 6/11, 2/12, 08/14, 11/2/2015, 9/20/16, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/27/21, 1/21/22

MA UM Committee approval: 12/31/23, 12/31/24, 4/29/25