Geisinger

# POLICIES AND PROCEDURE MANUAL

**Policy: MBP 63.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Ixempra (ixabepilone)**

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**I. Policy:**
Ixempra (ixabepilone)

**II. Purpose/Objective:**
To provide a policy of coverage regarding Ixempra (ixabepilone)

**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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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:**
Ixempra (ixabepilone) is a semi-synthetic analog of epothilone B. Ixabepilone binds directly to β-tubulin subunits on microtubules, leading to suppression of microtubule dynamics. Ixabepilone suppresses the dynamic instability of αβ-II and αβ-III microtubules and blocks cells in the mitotic phase of the cell division cycle, leading to cell death.

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

**GRANDFATHER PROVISION** – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Ixempra (ixabepilone) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Physician provided documentation of use in combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients who are taxane or anthracycline-resistant, or taxane-resistant with a contraindication to anthracyclines **OR**
- Physician provided documentation of use as a monotherapy for the treatment of metastatic or locally advanced breast cancer with tumors resistant or refractory to anthracyclines, taxanes and capecitabine. **AND**
- Patient does not have a history of a severe (Common Toxicity Criteria grade 3/4) hypersensitivity reaction to agents containing Cremophor® EL or its derivatives (polyoxyethylated castor oil) **AND**
- Medical record documentation of neutrophil count ≥1500 cells/$mm^3$ **AND**
- Medical record documentation of platelet count ≥100,000 cells/$mm^3$ **AND**
- If used with capecitabine, medical record documentation that AST or ALT are not greater than 2.5 times the upper limit of normal (ULN) or bilirubin is not greater than 1 times the ULN

For purposes of this policy:

- Anthracycline resistance is defined as progression while on therapy or within 6 months in the adjuvant setting or 3 months in the metastatic setting.

- Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or 4 months in the metastatic setting.

**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 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.

**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.**

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

**Devised:** 7/9/08

**Revised:** 02/10 (clarification of indication), 08/14, 3/24/15 (formatting, auth duration), 3/28/19 (grandfather), 12/19/22 (LOB carve out, Medicaid PARP statement, Medicaid Business Segment)

**Reviewed:** 2/12; 08/14, 3/16, 3/30/17, 3/29/18, 1/1/20, 1/1/21, 12/21/21, 12/6/23