Ixabepilone (Ixempra®)

NDC CODE(S) 70020-1910-XX IXEMPRA 15MG Solution Reconstituted (R-PHARM US)
70020-1911-XX IXEMPRA 45MG Solution Reconstituted (R-PHARM US)

DESCRIPTION

Ixabepilone, a semisynthetic analog of epothilone B, is the first FDA-approved epothilone antineoplastic agent. Ixabepilone functions as a microtubule stabilizer or microtubule inhibitor. Microtubules are important cellular structures that are involved in cell division. By binding to subunits of microtubules within cells, ixabepilone stabilizes the formation of microtubule bundles, thus inhibiting the natural action of the microtubules. This leads to G2/M phase cell cycle arrest during mitosis (cell division) leading to apoptosis or cell death.

POLICY

- Ixabepilone for the treatment of breast cancer is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Ixabepilone for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

:

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**

Universal Criteria

- If used in combination with capecitabine, the patient must not have an AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN; **AND**

Breast Cancer

- Patient has metastatic or recurrent unresectable disease; **AND**
  - Used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
    - Patient's disease is hormone receptor negative; **OR**
    - Patient's disease is hormone receptor positive with visceral crisis or is refractory to endocrine therapy; **OR**
  - Used in combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease; **AND**
    - Patient's disease is hormone receptor negative; **OR**
    - Patient's disease is hormone receptor positive and used with or without endocrine therapy; **OR**
- Patient has locally advanced or metastatic disease; **AND**
  - Patient has failed on an anthracycline* and a taxane** (or taxane resistant and further anthracycline therapy is contraindicated); **AND**
    - Used in combination with capecitabine; **OR**
    - Used as a single agent after failure on capecitabine

**Anthracycline resistance: defined as progression of disease while on therapy or within 6 months in the adjuvant setting, or 3 months in the metastatic setting.*

***Taxane resistance: defined as progression of disease while on therapy or within 12 months in the adjuvant setting, or 4 months in the metastatic setting.*

RENEWAL CRITERIA

- Patient continues to meet universal and other indication- specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: peripheral neuropathy, myelosuppression (neutropenia, leukopenia, anemia, and thrombocytopenia), hepatic impairment, hypersensitivity reactions, cardiac ischemia, impaired cardiac function, etc.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Breast Cancer	40 mg/m² administered intravenously (IV) over 3 hours every 21 days. *(Doses for patients with a BSA > 2.2 m^2 should be calculated based on 2.2 m^2)*

LENGTH OF AUTHORIZATION

Coverage is provided for six months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 90 billable units every 21 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice

Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Ixempra [package insert]. Princeton, NJ; R-Pharm US LLC; January 2016. Accessed April 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ixabepilone. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2021.
3. Thomas ES, Gomez HL, Li RK, et al. Ixabepilone plus capecitabine for metastatic breast cancer progressing after anthracycline and taxane treatment. J Clin Oncol. 2007 Nov 20;25(33):5210-7. doi: 10.1200/JCO.2007.12.6557.
4. Perez EA, Lerzo G, Pivot X, et al. Efficacy and safety of ixabepilone (BMS-247550) in a phase II study of patients with advanced breast cancer resistant to an anthracycline, a taxane, and capecitabine. J Clin Oncol. 2007 Aug 10;25(23):3407-14. doi: 10.1200/JCO.2006.09.3849.
5. Lexi-Comp Online. (2021, February). AHFS DI. *Ixabepilone*. Retrieved May 3, 2021 from Lexi-Comp Online with AHFS.
6. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2020, November). *Ixabepilone*. Retrieved May 3, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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