# Ixabepilone (Ixempra®)

## 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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

## POLICY

## INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- In combination with capecitabine for patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated
- As a single agent for patients with metastatic or locally advanced breast cancer whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine

Compendial Uses

Breast Cancer

All other indications are considered experimental/investigational and not medically necessary.

## DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status testing results, where applicable.

## COVERAGE CRITERIA

### Breast Cancer

Authorization of 12 months may be granted for treatment of breast cancer when any of the following criteria are met:

- Member has human epidermal growth factor receptor 2 (HER2)-negative locally advanced, recurrent unresectable or metastatic disease or disease with no response to preoperative systemic therapy, as a single agent; or
- Member has human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable or metastatic disease or disease with no response to preoperative systemic therapy, in combination with trastuzumab as fourth line therapy and beyond; or

- The requested medication will be used in combination with capecitabine for treatment of metastatic or locally advanced disease when the following criteria are met:
  - The cancer is resistant to treatment with an anthracycline and a taxane, or is taxane resistant and further anthracycline therapy is contraindicated; and
  - Member does not have aspartate aminotransferase (AST) or alanine aminotransferase (ALT) level greater than 2.5 times the upper limit of normal (ULN) or bilirubin greater than 1 time the ULN.

**CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

**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.

**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).

**REFERENCES**

1. Ixempra [package insert]. Princeton, NJ: R-Pharm US LLC; January 2023.
2. The NCCN Drugs & Biologics Compendium© 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 28, 2025.

**EFFECTIVE DATE** 9/30/2026

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