Reference number(s)
1897-A

SPECIALTY GUIDELINE MANAGEMENT

IXEMPRA (ixabepilone)

POLICY

I. 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.

A. FDA-Approved Indications
   1. In combination with capecitabine for the treatment of 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
   2. Monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine

B. Compendial Uses
   1. Human epidermal growth factor receptor 2 (HER2)-negative recurrent or stage IV (M1) breast cancer
   2. HER2-positive recurrent or stage IV (M1) breast cancer in combination with trastuzumab

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: HER2 status testing results

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer
Authorization of 12 months may be granted for treatment of breast cancer when any of the following criteria are met:
1. Member has human epidermal growth factor receptor 2 (HER2)-negative recurrent or metastatic disease, as a single agent; or
2. Member has human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic disease, in combination with trastuzumab; or
3. Ixempra will be used in combination with capecitabine for treatment of metastatic or locally advanced disease when the following criteria are met:
   a. Member has failed an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated; and
   b. 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.

IV. CONTINUATION OF THERAPY

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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

V. REFERENCES

1. Ixempra [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; January 2016.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 24, 2020.

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.