Reference number(s)
C22977-A

Ixempra (ixabepilone)

PROGRAM RATIONALE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by Clover Health for Ixempra.

CRITERIA FOR APPROVAL

1. What is the patient's diagnosis?
   a. Breast cancer
   b. Other

2. Is the patient currently receiving therapy with the requested medication?
   Yes
   No

Continuation criteria

3. Is the patient receiving benefit from therapy with the requested medication as defined as no evidence of unacceptable toxicity and no evidence of disease progression while on the current regimen?
   Yes
   No

Initiation criteria

20. Does the patient have human epidermal growth factor receptor 2 (HER2)-negative recurrent or metastatic disease? **If 'Yes', documentation of HER2 status testing results must be submitted upon request.**
    Yes
    No
21. Will the requested medication be used as a single agent?
    Yes
    No
22. Does the patient have human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic disease? **If 'Yes', documentation of HER2 status testing results must be submitted upon request.**
    Yes
    No
23. Will the requested medication be used in combination with trastuzumab?
    Yes
    No
24. Will the requested medication be used for metastatic or locally advanced disease?
    Yes
    No

25. Has the patient tried and failed an anthracycline and a taxane?

Yes
No

26. Is the cancer taxane resistant and the patient has a contraindication to further anthracycline therapy?
    Yes
    No
27. Does the patient 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?
    Yes
    No

SUMMARY OF EVIDENCE

1. Ixempra [package insert]. Halle/Westfalen, Germany: Baster Oncology GmbH; February 2022.

EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.