Ixempra (ixabepilone)

Override	Approval Duration
Prior Authorization	1 year

Medication
Ixempra (ixabepilone)

APPROVAL CRITERIA

Requests for Ixempra (ixabepilone) may be approved if the following criteria are met:

I. Individual has a diagnosis of breast cancer, metastatic or locally advanced; **AND**
II. *Any* of the following indications:

A. As a monotherapy in individuals treated with two prior lines of therapy (Label, NCCN 2A); **OR**
B. In combination with capecitabine in individuals previously treated with two lines of therapy, or whose cancer is taxane resistant and further anthracycline therapy is contraindicated (Label); **OR**
C. In combination with trastuzumab (or trastuzumab biosimilars) in individuals with disease resistant to treatment with taxanes (NCCN 2A); **OR**
D. As fourth-line therapy and beyond in combination with trastuzumab (or trastuzumab biosimilars) in the treatment of an individual with locally recurrent or metastatic HER2-positive breast cancer with either (NCCN 2A);
    1. Hormone receptor-negative disease; **OR**
    2. Hormone receptor-positive with or without endocrine therapy; **OR**
E. As single agent therapy for recurrent unresectable or stage IV HER2-negative disease that is HR-positive with visceral crisis or endocrine therapy refractory used in *one* of the following lines of therapy (NCCN 2A):
    1. As first-line therapy if no germline BRCA 1/2 mutation; **OR**
    2. As second-line therapy if not a candidate for fam trastuzumab deruxetecan-nxki; **OR**
    3. As third-line therapy and beyond;

OR

F. As single agent therapy for recurrent unresectable or stage IV triple negative breast cancer (TNBC) used in one of the following lines of therapy (NCCN 2A):
    1. First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**
    2. ~~2.~~ Second-line therapy and beyond.

Requests for Ixempra (ixabepilone) may not be approved for any of the following:

I. If the baseline neutrophil count is <1500 cells/mm^3 or the platelet count is < 100,000 cells/mm^3; **OR**
II. If Ixempra is used in combination with capecitabine and individual has hepatic impairment defined as AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN; **OR**

III. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 16, 2024.
    a. Breast Cancer. V5.2023. Revised December 5, 2023.
6. 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;25:3407-3414. Available at: http://www.ncbi.nlm.nih.gov/pubmed/17606974.
7. Roché H, Yelle L, Cognetti F, et al. Phase II clinical trial of ixabepilone (BMS-247550), an epothilone B analog, as first-line therapy in patients with metastatic breast cancer previously treated with anthracycline chemotherapy. J Clin Oncol. 2007;25(23):3415-3420. doi:10.1200/JCO.2006.09.7535. Available at: https://ascopubs.org/doi/10.1200/JCO.2006.09.7535?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed#T1.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.