CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Microtubule Inhibitor) – Ixempra Utilization Management Medical Policy
- Ixempra® (ixabepilone intravenous infusion – R-Pharm US)

REVIEW DATE: 01/14/2026

OVERVIEW

Ixempra, a microtubule inhibitor, is indicated in combination with capecitabine for the treatment of 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.[1] Ixempra is indicated as monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.

Anthracycline resistance is defined as progression while on therapy or within 6 months in the adjuvant setting or 3 months in the metastatic setting.[1] Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or 4 months in the metastatic setting.

Guidelines

The National Comprehensive Cancer Network (NCCN) **breast cancer** (version 5.2025 – October 16, 2025) clinical practice guidelines and Compendium recommend Ixempra as a single agent for invasive recurrent unresectable locoregional or invasive stage IV human epidermal growth factor receptor 2 (HER2)-negative disease and HER2-positive disease (with visceral crisis or endocrine therapy refractory).[2,3] It can be used in fourth-line therapy and beyond in combination with trastuzumab for HER2-positive disease. Ixempra is also recommended for locoregional or metastatic triple-negative breast cancer. Ixempra is recommended for inflammatory disease as a single agent for patients with no response to preoperative systemic therapy, or recurrent unresectable locoregional or stage IV HER2-negative disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Ixempra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Ixempra as well as the monitoring required for adverse events and long-term efficacy, approval requires Ixempra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ixempra is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has recurrent unresectable local or regional disease; OR
     - **ii.** Patient has metastatic disease; OR
     - **iii.** Patient has no response to preoperative systemic therapy; AND
   - **C)** Ixempra is prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** Each dose must not exceed 40 mg/m^2 administered intravenously given once in each 21-day cycle; OR
   - **B)** Each dose must not exceed 16 mg/m^2 administered intravenously given up to three times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ixempra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ixempra® intravenous infusion [prescribing information]. Princeton, NJ: R-Pharm US; January 2023.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 12, 2026. Search term: ixabepilone.
3. The NCCN Breast Cancer Clinical Practice Guidelines (version 5.2025 – October 16, 2025). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 12, 2026.
4. Rugo HS, Campone M, Amadori D, et al. A randomized, phase II, three-arm study of two schedules of ixabepilone or paclitaxel plus bevacizumab as first-line therapy for metastatic breast cancer. *Breast Cancer Res Treat*. 2013;139:411-419.
5. Rugo HS, Barry WT, Moreno-Aspitia A, et al. Randomized phase III trial of paclitaxel once per week compared with nanoparticle albumin-bound Nab-paclitaxel once per week or ixabepilone with bevacizumab as first-line chemotherapy for locally recurrent or metastatic breast cancer: CALGB 40502/NCCTG N063H (Alliance). *J Clin Oncol*. 2015;33:2361-2369.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/20/2023
Annual Revision	No criteria changes	01/08/2025
Update	04/21/2025: The policy name was changed from "Oncology (Injectable) – Ixempra UM Medical Policy" to "Oncology (Injectable – Microtubule Inhibitor) – Ixempra UM Medical Policy".	N/A
Annual Revision	No criteria changes	01/14/2026

N/A – Not applicable.