PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Ixempra Prior Authorization Policy
- Ixempra® (ixabepilone intravenous infusion – R-Pharm US)

REVIEW DATE: 12/21/2022

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 4.2022 – June 21, 2022) clinical practice guidelines 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 in combination with trastuzumab for HER2-positive disease.[2,3] 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 human epidermal growth factor receptor 2 (HER2)-negative disease and in combination with trastuzumab for HER2-positve disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ixempra. All approvals are provided for the duration noted below. 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 criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following criteria (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.

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 2022.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 19, 2022. Search term: ixabepilone.
3. The NCCN Breast Cancer Clinical Practice Guidelines (version 4.2022 – June 21, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 19, 2022.