Medical Policy:

Ixempra® (ixabepilone)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.153	February 16, 2024	

Definitions

Ixempra (ixabepilone): is a semisynthetic analog of epothilone B, a microtubule stabilizing agent. Ixabepilone directly binds to beta-tubulin subunits on microtubules and promotes tubulin polymerization and microtubule stabilization via inhibition of depolymerization. Microtubule stabilization leads to microtubule bundles, and the formation of microtubule bundles is plasma ixabepilone concentration-dependent. Alterations in spindle formation cause G2/M phase cell cycle arrest, which causes apoptosis. In addition to direct antitumor activity from cell cycle arrest, ixabepilone has antiangiogenic activity. Normally, microtubules modulate interactions with growth factors. In addition, Ixabepilone appears to have a low susceptibility to various mechanisms involved in the development of tumor resistance. Ixabepilone possesses low susceptibility to multiple tumor resistance mechanisms including efflux transporters such as MRP-l and P-glycoprotein (P-gp).

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

90 billable units per 21 days

Guideline

I. Initial Approval Criteria

Ixempra (ixabepilone) may be considered medically necessary when any of the following selection criteria is met:

1. **Breast Cancer**
   A. The member has a diagnosis of recurrent or metastatic breast cancer and Ixempra (ixabepilone) is being used for any of the following:
      i. In combination with capecitabine for disease resistant to treatment with an anthracycline and a taxane **OR** whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated; **OR**

      As a single agent in members whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine

Limitations/Exclusions

Ixempra (ixabepilone) is not considered medically necessary when any of the following selection criteria is met:

1. Ixempra is being used as adjuvant chemotherapy.
2. Dosing exceeds single dose limit of 40mg/m^2 of Ixempra.
3. Contraindicated with capecitabine in patients with AST or ALT greater than 2.5 times the upper limit of normal (ULN) or bilirubin greater than one times ULN due to increased risk of toxicity and neutropenia-related death.
4. Member has disease progression while taking Ixempra.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug including peripheral neuropathy, myelosuppression, hepatic impairment, hypersensitivity reactions, impaired cardiac function, cardiac ischemia.

Dosage/Administration

Indication	Dose
Breast Cancer	40 mg/m^2 IV over 3 hours, given every 3 weeks. Doses for patients with body surface area greater than 2.2 m^2 should be calculated based on 2.2 m^2.

Applicable Procedure Codes

Code	Description
J9207	Injection, ixabepilone, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
70020-1910-xx	Ixempra 15 mg powder for injection
70020-1911-xx	Ixempra 45 mg powder for injection

ICD-10 Diagnoses

Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast

C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/16/2024	Annual Review: Initial Criteria: Breast Cancer: Removed: "In combination with trastuzumab for human epidermal growth factor receptor 2-positive recurrent or metastatic trastuzumab-exposed disease; AND ONE of the following: Hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative with visceral crisis HER2-negative and either hormone receptor-negative, or hormone receptor-positive and endocrine therapy refractory Progressive with no clinical benefit after three consecutive endocrine therapy regimens or with symptomatic visceral disease."
EmblemHealth & ConnectiCare	6/22/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	07/25/2022	Transferred policy to new template, updated billing codes
EmblemHealth & ConnectiCare	7/15/2019	Annual review

References

1. Ixempra prescribing information. Ixabepilone IV injection. Bristol-Myers Company, Princeton,NJ. 2016.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.

3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2017