

Ixempra[®] (ixabepilone) (Intravenous)

Document Number: IC-0072

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Date of Origin: 01/01/2012

Dates Reviewed: 12/2011, 02/2013, 11/2013, 06/2014, 05/2015, 04/2016, 04/2017, 04/2018, 05/2019,
05/2020

I. Length of Authorization

Coverage will be for six months and is eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Ixempra 15 mg powder for injection: 2 vials per 21 days
- Ixempra 45 mg powder for injection: 2 vials per 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 90 billable units every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Universal Criteria ¹

- If used in combination with capecitabine, the patient must not have an AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN; **AND**

Breast Cancer ^{1,2}

- Patient has metastatic or recurrent disease \neq ²; **AND**
 - Must be used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
 - Patient's disease is hormone receptor negative; **OR**
 - Patient's disease is hormone receptor positive with visceral crisis or is refractory to endocrine therapy; **OR**
 - Must be used in combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease; **AND**
 - Patient's disease is hormone receptor negative; **OR**

- Patient’s disease is hormone receptor positive and used with or without endocrine therapy; **OR**
- Patient has locally advanced or metastatic disease †¹; **AND**
 - Patient has failed on an anthracycline* and a taxane** (or taxane resistant and further anthracycline therapy is contraindicated); **AND**
 - Must be used in combination with capecitabine; **OR**
 - Must be used as a single agent after failure on capecitabine

**Anthracycline resistance: defined as progression of disease while on therapy or within 6-months in the adjuvant setting, or 3-months in the metastatic setting.*

***Taxane resistance: defined as progression of disease while on therapy or within 12-months in the adjuvant setting, or 4-months in the metastatic setting.*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria ¹

Authorizations can be renewed based on the following criteria:

- Patient continues to meet universal or indication specific criteria as in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: peripheral neuropathy, myelosuppression (neutropenia, leukopenia, anemia, and thrombocytopenia), hepatic impairment, hypersensitivity reactions, cardiac ischemia, impaired cardiac function, etc.

V. Dosage/Administration

Indication	Dose
Breast Cancer	40 mg/m ² administered intravenously (IV) over 3 hours every 21 days. <i>(Doses for patients with a BSA > 2.2 m² should be calculated based on 2.2 m²)</i>

VI. Billing Code/Availability Information

HCPCS code:

- J9207 – Injection, ixabepilone, 1mg; 1 billable unit = 1 mg

NDC:

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

VII. References

1. Ixempra [package insert]. Princeton, NJ; R-Pharm US LLC; January 2016. Accessed April 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ixabepilone. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2020.
3. CGS, Administrators, LLC. Local Coverage Article: Billing and Coding: Ixabepilone; Ixempra Injection -J9207 (A57257). Centers for Medicare & Medicaid Services, Inc. Updated on 09/18/2019 with effective date 09/26/2019. Accessed April 2020.
4. Palmetto GBA. Local Coverage Article: Billing and Coding: Chemotherapy (A56141). Centers for Medicare & Medicaid Services, Inc. Updated on 03/24/2020 with effective date 04/03/2020. Accessed April 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

IXEMPRA® (ixabepilone) Prior Auth Criteria

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ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): J & M	NCD/LCD/LCA Document (s): A56141
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAAA	

Jurisdiction(s): 15	NCD/LCD/LCA Document (s): A57257
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57257&bc=gAAAAAAAAAAAA&	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC