Ixabepilone (Ixempra®)

Place of Service
Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: J9207 per 1 mg

Condition(s) listed in policy (see criteria for details)

• Breast cancer

AHFS therapeutic class: Antineoplastic Agent

Mechanism of action: Microtubule inhibitor

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Ixempra® (ixabepilone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer

- 1. Either of the following:
 - a. Locally advanced, recurrent unresectable, or metastatic disease, OR
 - b. Inflammatory breast cancer which has had no response to preoperative systemic therapy

AND

- 2. One of the following:
 - a. HER2-negative and hormone receptor positive disease, and meets all of the following:
 - i. Effective 10/30/2023 and after. used as a single agent, and
 - ii. One of the following:
 - 1. First-line therapy if no germline BRCA 1/2 mutation, OR
 - 2. Second-line therapy if not a candidate for fam-trastuzumab deruxtecan-nxki, OR
 - 3. Third-line therapy and beyond

OR

- b. HER2-positive disease and either of the following:
 - i. *Effective through 10/29/2023*: Being used with trastuzumab as third line and beyond therapy, OR
 - ii. *Effective 10/30/2023 and after*. Being used with trastuzumab as fourth line and beyond therapy

Or

- c. Single agent therapy for triple negative disease and meets one of the following:
 - i. First-line therapy if PD-L1 CPS < 10 and no germline BRCA 1/2 mutation,
 OR
 - ii. Second-line therapy and beyond

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Covered Doses

Up to 40 mg/m² every 3 weeks

Coverage Period

Cover indefinitely

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Ixempra® (ixabepilone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

15 mg Ixempra single use vial, supplied with diluent for Ixempra, 8 mL. 45 mg Ixempra single use vial, supplied with diluent for Ixempra, 23.5 mL.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Ixempra® (ixabepilone) [Prescribing Information]. Princeton, NJ: R-Pharm US LLC; 1/2023.
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Ixempra (2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Breast Cancer (Volume 4.2023). Available at http://www.nccn.org

(7) Policy Update

Date of last review: 3Q2023 Date of next review: 3Q2024

Changes from previous policy version:

- Section (2): Breast cancer
 - Expand coverage for HER2-negative/hormone-receptor positive disease to include first line, second line, and third line therapy without specified prior treatments. Effective 10/30/2023, will require use as a single agent. Rationale: NCCN category 2A support
 - Effective 10/30/2023 and after, will restrict coverage for HER2 positive disease to be used as fourth line and beyond Rationale: NCCN category 2A support
 - Clarify coverage for triple negative disease

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BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

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