POLICY NUMBER UM ONC_1248	**SUBJECT** Ixempra™(ixabepilone)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 09/18/13, 10/06/14, 11/12/14, 04/11/16, 02/06/17, 02/01/18, 02/13/19, 12/11/19, 02/12/20	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 09/18/13, 10/06/14, 11/12/14, 04/11/16, 02/06/17, 02/01/18, 02/13/19, 12/11/19, 02/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Ixempra (ixabepilone) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. Breast Cancer
    a. The member has a diagnosis of recurrent or metastatic breast cancer and Ixempra (ixabepilone) is being used as any of the following:
        i. In combination with capecitabine **OR**
        ii. In combination with trastuzumab for human epidermal growth factor receptor 2-positive disease **OR**
        iii. As a single agent.

III. EXCLUSION CRITERIA

1. Ixempra is being used as adjuvant chemotherapy.
2. Dosing exceeds single dose limit of 40mg/m^2 of Ixempra.
3. 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.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATACHMENTS

None

VII. REFERENCES

1. Ixempra prescribing information. Ixabepilone IV injection. Bristol-Myers Company, Princeton,NJ. 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.