Blue Cross Blue Shield Blue Care Network of Michigan

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Retired
Effective Date: 02/02/2023

Halaven® (eribulin mesylate)

HCPCS: J9179

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. Prescribed by or in consultation with an oncologist
   b. Diagnosis of metastatic breast cancer
      i. Prior treatment failure with at least two chemotherapeutic regimens
      ii. Use as monotherapy or in combination with trastuzumab if human epidermal growth factor receptor 2 (HER2)-positive for
         1. Symptomatic visceral disease or visceral crisis
         2. Hormone-receptor negative or hormone-receptor positive but refractory to endocrine therapy
   c. Diagnosis of unresectable or metastatic liposarcoma
      i. Prior treatment with an anthracycline-containing regimen
      ii. Use as monotherapy
   d. Should not be used if prior treatment failure has occurred with Havalen

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time
   c. Renewal Criteria: Treatment continued until unacceptable toxicity or disease progression

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Halaven is indicated for the treatment of metastatic breast cancer in patients who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease and unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

- The 2022 National Comprehensive Cancer Network (NCCN) treatment guidelines for breast cancer expand on the FDA approved indication. Guidelines recommend use in as monotherapy for HER2-negative disease or in combination with Herceptin if the tumor is HER2-positive and refractory to endocrine therapy when symptomatic visceral disease is present.

- Halaven has not been studied in combination with other therapies outside of use with Herceptin in HER2-positive visceral disease and should be used as monotherapy.

- There are no studies to support use of Halaven following failure of its use. NCCN guidelines also do not recommend use of Halaven following a previous failure.

References:

1. Halaven [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; December 2021.
2. National Comprehensive Cancer Network. Breast cancer (Version 4.2022). 2022 June 21. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on August 19, 2022.
3. National Comprehensive Cancer Network. Soft tissue sarcomas (Version 2.2022). 2022 May 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed on August 19, 2022.
4. Schoffski P, Chawla S, Maki RG, et al. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomized, open-label, multicentere, phase 3 trial. Lancet. 2016 Apr 16; 387 (10028): 1629 – 37.
5. Cortes J, O'Shaughnessy J, Loesch D, et al. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomized study. Lancer. 2011; 377: 914 – 23.
6. Schoffski P, Ray-Coquard IL, Cioffiet A, et al. Activity of eribulin mesylate in patients with soft-tissue sarcoma: a phase 2 study in four independent histological subtypes. Lancet Oncology. 2011 Oct; 12 (11): 1045 - 52.
7. Schoffski P, Chawla S, Maki RG, et al. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomized, open-label, multicentre, phase 3 trial. Lancet. 2016 Apr 16; 387 (10028): 1629 – 37.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.9</td><td>Effective Date: 02/02/2023</td><td>Retiring policy as drug will no longer be part of the prior authorization program</td></tr>
<tr><td>1.8</td><td>Effective Date: 10/06/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.7</td><td>Effective Date: 10/07/2021</td><td>Annual review of policy. No changes were made to the criteria</td></tr>
<tr><td>1.6</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.5</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>1.4</td><td>Effective Date: 01/01/2020</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.3</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
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<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.1</td><td>Effective Date: 11/09/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 08/11/2016</td><td>New Coverage Guidelines
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*