Halaven (eribulin mesylate)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Halaven (eribulin mesylate)

APPROVAL CRITERIA

Requests for Halaven (eribulin mesylate) may be approved if the following criteria are met:

I. Individual has a diagnosis of locally recurrent or metastatic breast cancer (Label, NCCN 2A); **AND**
II. Individual is using as monotherapy; **AND**
III. Individual is using as a single line of therapy; **AND**
IV. Individual has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease;

OR

V. Individual has a diagnosis of locally recurrent or metastatic HER2 positive breast cancer (NCCN 2A);
AND
VI. In one of the following ways:
   A. Individual is using in combination with trastuzumab (or trastuzumab biosimilars);
   OR
   B. Individual is using in combination with Margenza (margetuximab-cmbk) as third line therapy;
AND
VII. Individual has symptomatic visceral disease;
OR
VIII. Individual has either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease;

OR

IX. Individual has a diagnosis of locally recurrent or metastatic soft tissue sarcoma (Label, NCCN 1, 2A); **AND**
X. Individual is using as monotherapy; **AND**
XI. Individual is using as a single line of therapy; **AND**
XII. Individual has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease.

Requests for Halaven (eribulin mesylate) may not be approved for the following criteria:

I. Individual has a diagnosis of head and neck cancer; **OR**

II. Individual has a diagnosis of non-small cell lung cancer; **OR**
III. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. 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 randomised study. Lancet. 2011;377(9769):914-923. doi:10.1016/S0140-6736(11)60070-6 Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60070-6/fulltext. Accessed January 18, 2022.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 18, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Kaufman PA, Awada A, Twelves C, et al. Phase III open-label randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. J Clin Oncol. 2015;33(6):594-601. doi:10.1200/JCO.2013.52.4892. Available at: https://ascopubs.org/doi/full/10.1200/JCO.2013.52.4892. Accessed January 18, 2022.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2022.
    a. Breast Cancer. V2.2022. Revised December 20, 2021.
    b. Soft Tissue Sarcoma. V2.2021. Revised April 28, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.