SmartHealth

Ascension

Eribulin Mesylate

(Halaven®) J9179 (0.1 mg)

Covered with prior authorization

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

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

OR

- Individual has a diagnosis of locally recurrent or metastatic HER-2 positive breast cancer (NCCN 2A); **AND**
- In one of the following ways:
    - Individual is using in combination with trastuzumab (or trastuzumab biosimilars); **OR**
    - Individual is using in combination with Margenza (margetuximab-cmkb) as third line therapy;

  AND
- Individual has symptomatic visceral disease; **OR**
- Individual has either hormone receptor-negative disease or hormone-receptor positive and endocrine refractory disease;

OR

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

Requests for Halaven® (eribulin mesylate) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Halaven® (eribulin mesylate) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Individual has a diagnosis of head and neck cancer; **OR**
- Individual has a diagnosis of non-small cell lung cancer.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Halaven® is a non-taxane microtubule dynamics inhibitor that is a synthetic analogue of halichondrin B, a product isolated from a marine sponge. Although the exact mechanism is unknown, it is believed to work through inhibition of the growth phase of microtubule dynamics, without affecting the shortening phase, sequestering tubulin into nonproductive aggregates. The FDA approved indications for Halaven® include metastatic breast cancer or unresectable or metastatic liposarcoma. The National Comprehensive Cancer Network (NCCN) provides additional recommendations with a category 1 and 2A level of evidence for the uses in invasive breast cancer and soft tissue sarcoma.

Key References Accessed 8/2022:

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 randomized 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.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
4. 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.

5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. 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.
    a. Breast Cancer. V2.2022. Revised December 20, 2021.
    b. Soft Tissue Sarcoma. V2.2021. Revised April 28, 2021.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.