Reference number(s)
1893-A

Specialty Guideline Management eribulin-Halaven

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Halaven	eribulin mesylate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1,2]

- Halaven is indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.
- Halaven is indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Compendial Uses[3]

- Breast cancer
- Soft tissue sarcoma
    - Retroperitoneal/intra-abdominal
    - Pleomorphic rhabdomyosarcoma
    - Extremity/body wall, head/neck
    - Dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma

- Epithelioid hemangioendothelioma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status testing results, where applicable.

Coverage Criteria

Breast Cancer[1-3]

Authorization of 12 months may be granted for treatment of recurrent unresectable or metastatic breast cancer or breast cancer with no response to preoperative systemic therapy when either of the following criteria is met:

- The requested medication will be used as a single agent for HER2-negative disease; or
- The requested medication will be used in combination with margetuximab-cmkb or trastuzumab for HER2-positive disease as fourth line therapy and beyond.

Soft Tissue Sarcoma[1-3]

Authorization of 12 months may be granted for treatment of any of the following types of soft tissue sarcoma, as single-agent therapy:

- Retroperitoneal/intra-abdominal
- Pleomorphic rhabdomyosarcoma
- Extremity/body wall, head/neck
- Dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma
- Epithelioid hemangioendothelioma

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Halaven [package insert]. Nutley, NJ: Eisai Inc.; September 2022.
2. Eribulin [package insert]. Elmwood Park, NJ: Glenmark Pharmaceuticals Inc., USA; October 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 27, 2025.