Eribulin Mesylate (Halaven®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

- 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

- 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

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

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.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Halaven (Eribulin Mesylate)	Breast Cancer	Route of Administration: Intravenous 1.4mg/m² on days 1 and 8 of a 21-day cycle
Halaven (Eribulin Mesylate)	Soft Tissue Sarcoma, including Liposarcoma	Route of Administration: Intravenous 1.4mg/m² on days 1 and 8 of a 21-day cycle

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE 9/30/2026