Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: PA.CP.PHAR.318
Effective Date: 01/2018
Last Review Date: 10/2025

Description
Eribulin mesylate (Halaven®) is a microtubule dynamics inhibitor.

FDA Approved Indication(s)
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
- Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen

Policy/Criteria
It is the policy of PA Health & Wellness ® that Halaven is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is metastatic, recurrent, unresectable, or that has no response to preoperative systemic therapy;
5. Prescribed in one of the following ways (a, b, or c):
   a. In combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease as fourth-line therapy or beyond;
   b. In combination with Margenza™ for HER2-positive disease as fourth-line therapy or beyond;
   c. As a single agent for HER2-negative disease or triple negative breast cancer (TNBC);
6. Request meets one of the following (a or b):
   a. Dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

B. Soft Tissue Sarcoma (must meet all):

1. Diagnosis of one of the following soft tissue sarcoma (STS) subtypes (a-e):
   a. Extremity/body wall and head/neck;
   b. Retroperitoneal/intra-abdominal;
   c. Pleomorphic rhabdomyosarcoma;
   d. Liposarcoma;

e. Epithelioid hemangioendothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is advanced, metastatic, recurrent, progressive or unresectable;
5. Prescribed as a single agent;
6. Prescribed as subsequent therapy for all STS subtypes;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy.
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA. PHARM.01) applies; or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
NCCN: National Comprehensive Cancer Network
STS: soft tissue sarcoma

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	1.4 mg/m^2 IV over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2
STS	1.4 mg/m^2 IV over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2

VI. Product Availability

Injection in a single-use vial: 1 mg/2 mL

VII. References

1. Halaven Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc.; September 2022. Available at: http://www.halaven.com. Accessed July 10, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 12, 2025.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 12, 2025.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 12, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9179	Injection, eribulin mesylate, 0.1 mg

Reviews, Revisions, and Approvals	Date
4Q 2018 annual review: no significant changes; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added COC; references reviewed and updated.	07/2018
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019
4Q 2020 annual review: for STS per NCCN recommendations – added "advanced" designation to extremity/body wall and head/neck STS; removed "progressive" and added "recurrent or stage IV" designation to retroperitoneal/intra-abdominal STS; added "advanced or metastatic" designation to pleomorphic rhabdomyosarcoma; added additional STS	10/2020

Reviews, Revisions, and Approvals	Date
subtype options: solitary fibrous tumor and UPS; added that Halaven should be used as subsequent therapy for all STS subtypes except angiosarcoma, solitary fibrous tumor, and UPS; references reviewed and updated.	
4Q 2021 annual review: added combination with Margenza and clarified combination with trastuzumab is for 3rd line therapy or beyond for breast cancer per NCCN Compendium; removed off-label indication for use in undifferentiated pleomorphic sarcoma per NCCN Compendium; references reviewed and updated.	10/2021
4Q 2022 annual review: removed coverage for angiosarcoma and solitary fibrous tumor as use is no longer supported by the NCCN Soft Tissue Sarcoma guidelines; references reviewed and updated.	10/2022
4Q 2023 annual review: for breast cancer, revised trastuzumab and Margenza combination therapy options with Halaven to be fourth-line therapy or beyond per NCCN update; simplified STS criteria to create separate criterion that disease is advanced, metastatic, recurrent, or unresectable; references reviewed and updated.	10/2023
4Q 2024 annual review: no significant changes; references reviewed and updated.	10/2024
4Q 2025 annual review: for STS, added liposarcoma and epithelioid hemangioendothelioma subtypes per NCCN compendium and guidelines; for initial approval criteria, extended approval duration from 6 months to 12 months; references reviewed and updated.	10/2025