Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: ERX.SPA.279
Effective Date: 12.01.18
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 or recurrent;
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 third line therapy or beyond;
   b. In combination with Margenza™ for HER2-positive disease as third line therapy or beyond;
   c. As a single agent for HER2-negative disease;
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)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Soft Tissue Sarcoma (must meet all)**:**

1. Diagnosis of one of the following soft tissue sarcoma (STS) subtypes (a, b, or c):
   a. Advanced, metastatic, or recurrent extremity/body wall and head/neck STS;
   b. Recurrent, unresectable, or stage IV retroperitoneal/intra-abdominal STS;
   c. Advanced or metastatic pleomorphic rhabdomyosarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Prescribed as a single agent;
5. Prescribed as subsequent therapy for all STS subtypes;
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).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Halaven for a covered indication and has received this medication for at least one 21-day cycle;
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).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

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 5minutes 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.; December 2021. Available at: http://www.halaven.com. Accessed June 22,2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 22,2022.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed June 22, 2022.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2022. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 22, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.11.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.09.19	11.19
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 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.	07.14.20	11.20
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.	08.05.21	11.21
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.	06.22.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.