Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: ERX.SPA.279
Effective Date: 12.01.18
Last Review Date: 11.18 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:

- Metastatic breast cancer in patients 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 in patients 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.

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 or b):
   a. In combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease;
   b. 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)*.

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. Metastatic or recurrent extremity/superficial trunk and head/neck STS;
   b. Unresectable or progressive retroperitoneal/intra-abdominal STS;
   c. Angiosarcoma or pleomorphic rhabdomyosarcoma (off-label);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. 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: 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).*

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

- Contraindication(s): none reported
- Boxed warning(s): none reported

Appendix D: General Information

- The NCCN recommends the use of Halaven as a single agent (for HER2-negative disease) or in combination with trastuzumab (for HER2-positive disease) for the treatment of metastatic or recurrent breast cancer:
  - With symptomatic visceral disease or visceral crisis, or
  - That is hormone receptor-negative, or hormone receptor-positive and endocrine therapy refractory.
- There are over 50 different histologic STS subtypes. While Halaven is only FDA-approved for the treatment of one subtype (liposarcomas), the NCCN recommends Halaven for STS with extremity/superficial trunk, head/neck, and retroperitoneal/intra-abdominal origins, as well as angiosarcoma and pleomorphic rhabdomyosarcoma. For all subtypes, the NCCN recommends Halaven to be used only as palliative therapy (category 1 for liposarcoma; 2A for all other subtypes).

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.; October 2016. Available at http://www.halaven.com. Accessed July 5, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 5, 2018.
3. National Comprehensive Cancer Network. Breast Cancer Version 1.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed July 5, 2018.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed July 5, 2018

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.11.18	11.18

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.

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