Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: LA.PHAR.318
Effective Date: 11.04.23
Last Review Date: 11.20.25~~12.03.24~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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.

It is the policy of Louisiana Healthcare Connections® 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 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;
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~~ 12 months

B. Soft Tissue Sarcoma (must meet all)**:**
1. Diagnosis of one of the following soft tissue sarcoma (STS) subtypes (a, b, c, d, or ~~e~~e):
   a. Extremity/body wall and head/neck ~~STS~~;
   b. Retroperitoneal/intra-abdominal ~~STS~~;
   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, 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).*

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

Approval duration: ~~6~~ 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.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 LA.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

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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 ~~12, 2024~~10, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~8, 2024~~12, 2025.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.~~2024~~2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August ~~8, 2024~~12, 2025.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version ~~2.2024~~1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August ~~8, 2024~~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	LDH Approval Date
Converted corporate policy to local policy.	06.25.23	10.05.23
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.	04.22.24	07.10.24
No significant changes; references reviewed and updated.	12.03.24	02.24.25
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	11.20.25	

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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