Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: CP.PHAR.318
Effective Date: 03.01.17
Last Review Date: 11.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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.

It is the policy of health plans affiliated with Centene Corporation® 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:
Medicaid/HIM – 6 months

Commercial – 6 months or to the member's renewal date, whichever is longer

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):
   a. Advanced, metastatic, or recurrent extremity/body wall and head/neck STS;
   b. Recurrent, unresectable or stage IV retroperitoneal/intra-abdominal STS;
   c. Angiosarcoma;
   d. Advanced or metastatic pleomorphic rhabdomyosarcoma;
   e. Solitary fibrous tumor;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For all STS subtypes except angiosarcoma and solitary fibrous tumor: Prescribed as subsequent therapy;
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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 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.; February 2021. Available at: http://www.halaven.com. Accessed August 5, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 5, 2021.
3. National Comprehensive Cancer Network. Breast Cancer Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 5, 2021.

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	P&T Approval Date
Removed requirement for negative history of congenital long QT syndrome and added an age limit for all covered indications, per the PA policy on safety precautions. Removed coverage of uterine sarcoma, as it is an NCCN 2b-rated recommendation. Changed approval duration periods from 3/6 months to 6/12 months.	08.23.17	11.17
4Q 2018 annual review: no significant changes; added commercial and HIM lines of business; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added COC; references reviewed and updated.	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 for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	08.05.21	11.21

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.