

Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: CP.PHAR.318

Effective Date: 03/17

Last Review Date: 03/17

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for eribulin mesylate for injection (Halaven®).

Policy/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. Meets a or b:
 - a. FDA approved use:
 - i. Prescribed for metastatic disease and member has a positive history for all of the following therapies:
 - a) At least 2 chemotherapeutic regimens in the metastatic setting;
 - b) An anthracycline in the adjuvant* or metastatic setting;
 - c) A taxane in the adjuvant* or metastatic setting;
 - b. Off-label NCCN recommended use:
 - i. Prescribed for metastatic or recurrent disease in one of the following ways (a or b):
 - a) As single-agent therapy for human epidermal growth factor receptor 2 (HER2)-negative disease characterized by (1, 2 or 3):
 - 1) Presence of symptomatic visceral disease or visceral crisis;
 - 2) Hormone receptor-negative disease**;
 - 3) Hormone receptor-positive disease** that is endocrine therapy refractory†;
 - b) In combination with trastuzumab for HER2-positive trastuzumab-exposed disease characterized by (1, 2 or 3):
 - 1) Presence of symptomatic visceral disease or visceral crisis;
 - 2) Hormone receptor-negative disease**;
 - 3) Hormone receptor-positive disease** that is endocrine therapy refractory†;
 3. Negative history for congenital long QT syndrome.

*Adjuvant therapy (therapy administered after the main treatment to help decrease the risk of cancer recurring).

**Hormone receptor-negative disease (estrogen receptor [ER] - and progesterone receptor [PR]-negative disease); hormone receptor-positive disease (ER- or PR-positive disease).

†Examples of endocrine therapies include anastrozole, letrozole, exemestane, fulvestrant, tamoxifen, toremifene, megestrol acetate, fluoxymesterone, ethinyl estradiol.

Approval duration: 3 months

B. Soft Tissue Sarcoma (must meet all):

1. Meets a or b:
 - a. FDA approved use:
 - i. Diagnosis of liposarcoma (soft tissue sarcoma [STS] subtype)*, and (a and b);
 - a) Disease is unresectable or metastatic;
 - b) Positive history for prior treatment with an anthracycline-containing regimen (e.g., a regimen containing doxorubicin or epirubicin);
 - b. Off-label NCCN recommended use:
 - i. Angiosarcoma or pleomorphic rhabdomyosarcoma as single-agent palliative therapy;
 - ii. Retroperitoneal/intraabdominal STS as single-agent palliative therapy for unresectable or progressive disease;
 - iii. Extremity/superficial trunk or head/neck STS as single-agent palliative therapy for Stage IV or recurrent disease with disseminated metastases;
2. History negative for congenital long QT syndrome.

**More than 50 STS histologic subtypes have been identified. Different subtypes have different propensities to spread to different locations. Location, histology and other variables are considerations around which therapy is organized.*

Approval duration: 3 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

1. The following NCCN recommended uses for Halaven, meeting NCCN categories 1, 2a, or 2b, are approved per the CP.PHAR.57 Global Biopharm Policy:
 - a. Uterine sarcoma.

II. Continued Approval

A. All Indications (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 6 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Halaven contains eribulin mesylate, a microtubule dynamics inhibitor. Eribulin mesylate is a synthetic analogue of halichondrin B, a product isolated from the marine sponge *Halichondria okadai*. Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. Eribulin exerts its effects via a tubulin-based antimetabolic mechanism leading to G2/M cell-cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged mitotic blockage. In addition, eribulin treatment of human breast cancer cells caused changes in morphology and gene expression as well as decreased migration and invasiveness in vitro. In mouse xenograft models of human breast cancer, eribulin treatment was associated with increased vascular perfusion and permeability in the tumor cores, resulting in reduced tumor hypoxia, and changes in the expression of genes in tumor specimens associated with a change in phenotype.

Formulations:

Halaven is available as follows:

- Injection: 1 mg/2 mL, in a single-use vial. One vial per carton.

FDA Approved Indications:

Halaven is a microtubule inhibitor/intravenous formulation indicated:

- Metastatic breast cancer
 - 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.
- Liposarcoma
 - Halaven is indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Appendices

Appendix A: Abbreviation Key

CTCAE: Common terminology criteria for adverse events

ER: Estrogen receptor

HER2: Human epidermal growth factor receptor 2

PR: Progesterone receptor

STS: Soft tissue sarcoma

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.

CLINICAL POLICY
Eribulin Mesylate

HCPCS Codes	Description
J9179	Injection, eribulin mesylate, 0.1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.	02/17	03/17

References

1. Halaven prescribing information. Woodcliff Lake, NJ: Eisai, Inc.; October 2016. Available at <http://www.halaven.com/pdfs/HALAVEN-Full-Prescribing-Information.pdf>. Accessed January 30, 2017.
2. Eribulin mesylate. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 30, 2017.
3. Breast cancer (Version 2.2016). National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 30, 2017.
4. Soft tissue sarcoma (Version 1.2017). National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 30, 2017.

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.

CLINICAL POLICY

Eribulin Mesylate

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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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NDCs, LCDs and Medicare Coverage articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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