Evolent Clinical Guideline 3164 for Halaven™ (eribulin)

Guideline Number:	Applicable Codes	
Evolent_CG_3164		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.		
© 2012 - 2026 Evolent. All rights Reserved.		
Original Date:	**Last Revised Date:**	**Implementation Date:**
February 2012	August 2026	August 2026

TABLE OF CONTENTS

STATEMENT **2**
PURPOSE 2
INDICATIONS **2**
BREAST CANCER 2
SOFT TISSUE SARCOMA 2
CONTRAINDICATIONS/WARNINGS **2**
EXCLUSION CRITERIA **3**
CODING AND STANDARDS **3**
CODES 3
APPLICABLE LINES OF BUSINESS 4
POLICY HISTORY **4**
LEGAL AND COMPLIANCE **4**
GUIDELINE APPROVAL 4
Committee *4*
DISCLAIMER 4
REFERENCES **6**

STATEMENT

Purpose

To define and describe the accepted indications for Halaven (eribulin) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used as a single agent for members with HER2-negative disease OR
- The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used in combination with trastuzumab/trastuzumab biosimilar for members with HER2-positive disease.

Soft Tissue Sarcoma

- The member has metastatic/unresectable liposarcoma with disease progression on anthracycline based therapy, and Halaven (eribulin) is being used as a single agent.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Dosing exceeds single dose limit of Halaven (eribulin) 1.4 mg/m^2.
- The member has disease progression on or after receiving Halaven (eribulin).
- Investigational use of Halaven (eribulin) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9179 - Injection, eribulin mesylate, 0.1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
August 2026	• Updated references
August 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1205 Halaven (eribulin) • Updated indication section • Updated references
August 2024	• Updated drug spelling

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or

drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Blay JY, et al. Eribulin versus dacarbazine in patients with leiomyosarcoma: subgroup analysis from a phase 3, open-label, randomised study. *Br J Cancer*. 2019 May;120(11):1026-1032. doi: 10.1038/s41416-019-0462-1.
2. Schöffski P, et al. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomised, open-label, multicentre, phase 3 trial. *Lancet*. 2016 Apr 16;387(10028):1629-37. doi: 10.1016/S0140-6736(15)01283-0.
3. Halaven prescribing information. Eisai Inc. Nutley, NJ 2022.
4. Clinical Pharmacology Elsevier Gold Standard 2026.
5. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
6. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
7. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
8. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
9. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
10. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.