Drug Policy:

Halaven™ (eribulin)

POLICY NUMBER UM ONC_1205	**SUBJECT** Halaven™ (eribulin)	**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 02/08/12, 12/11/13, 03/11/15, 04/11/16, 02/14/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 04/12/23, 04/10/24, 08/14/24	**APPROVAL DATE** August 14, 2024	**EFFECTIVE DATE** August 30, 2024	**COMMITTEE APPROVAL DATES** 02/08/12, 12/11/13, 03/11/15, 04/11/16, 02/14/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 04/12/23, 04/10/24, 08/14/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. 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.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

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

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Breast Cancer

1. 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
2. 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.

C. Soft Tissue Sarcoma

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

III. EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of Halaven (eribulin) 1.4 mg/m^2.

B. The member has disease progression on or after receiving Halaven (eribulin).

C. 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:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. 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.
4. 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).
5. 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.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. 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.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Rugo HS, et al. SOPHIA Clinical Trial. Margetuximab Versus Trastuzumab in Patients With Previously Treated HER2-Positive Advanced Breast Cancer (SOPHIA): Final Overall Survival Results From a Randomized Phase 3 Trial. J Clin Oncol. 2023 Jan 10;41(2):198-205.

B. Rugo HS, et al. SOPHIA Clinical Trial. Efficacy of Margetuximab vs Trastuzumab in Patients With Pretreated ERBB2-Positive Advanced Breast Cancer: A Phase 3 Randomized Clinical Trial. JAMA Oncol. 2021 Apr 1;7(4):573-584.

C. 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.

D. 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;387(10028):1629.

E. Halaven prescribing information. Eisai Inc. Nutley, NJ 2022.

F. Clinical Pharmacology Elsevier Gold Standard 2023.

G. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

I. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

J. 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.

K. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.