

Corporate Medical Policy

Eribulin Mesylate (Halaven[®])

File Name:	eribulin_mesylate_halaven
Origination:	9/2016
Last CAP Review:	4/2020
Next CAP Review:	4/2021
Last Review:	4/2020

Description of Procedure or Service

Eribulin Mesylate (Halaven[®]) is a non-taxane, microtubule dynamics inhibitor with a distinct mechanism of action from other classes of tubulin-targeted agents such as the taxanes, vinca alkaloids, and epothilones. It is a synthetic analog of halichondrin B, a product isolated from the rare marine sponge *Halichondria okadai*. Without affecting the shortening phase of microtubules, eribulin inhibits the growth phase of microtubules and sequesters tubulin into nonproductive aggregates leading to cell cycle blockage at the G₂/M phase, disruption of mitotic spindles, and eventually apoptotic cell death following prolonged mitotic blockage. It suppresses microtubule polymerization yet does not affect depolymerization. In vitro, eribulin caused changes in morphology and gene expression, and decreased migration and invasiveness of breast cancer cells.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Eribulin Mesylate (Halaven) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Eribulin Mesylate (Halaven) is covered

Eribulin Mesylate (Halaven) is considered medically necessary in the treatment of individuals with locally recurrent or metastatic breast cancer.

Eribulin Mesylate (Halaven) is considered medically necessary in combination with trastuzumab in the treatment of individuals with locally recurrent or metastatic HER2+ breast cancer.

Eribulin Mesylate (Halaven) is considered medically necessary in the treatment of individuals with unresectable or metastatic liposarcoma following at least two prior systemic therapy regimens for advanced disease, including one with an anthracycline (unless contraindicated).

Use of Eribulin Mesylate (Halaven) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

Eribulin Mesylate (Halaven[®])

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached

When Eribulin Mesylate (Halaven) is not covered

Eribulin Mesylate (Halaven) is considered not medically necessary and therefore not covered when above criteria are not met.

Eribulin Mesylate (Halaven) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Eribulin Mesylate (Halaven) is covered.”

Policy Guidelines

Administer 1.4 mg/m² intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.

Reduce dose in patients with hepatic impairment or with moderate or severe renal impairment.

Do not mix with other drugs or administer with dextrose-containing solutions.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9179, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Available at:
<http://www.halaven.com/pdfs/HALAVEN-Full-Prescribing-Information.pdf>

Medical Director review 9/2016

Eribulin Mesylate (Halaven®)

Specialty Matched Consultant Advisory Panel review 4/2017

Eisai Inc. Halaven (eribulin mesylate) injection, for intravenous use. Prescribing Information. Woodcliff Lake, NJ:Eisai; Revised 10/2016. Available at: <https://www.halaven.com/-/media/Files/Halaven/HALAVEN-Full-Prescribing-Information.pdf>. Accessed April 2018.

Specialty Matched Consultant Advisory Panel review 4/2018

Medical Director review 5/2018

Specialty Matched Consultant Advisory Panel review 4/2019

Specialty Matched Consultant Advisory Panel review 4/2020

Policy Implementation/Update Information

12/30/16 New policy developed. Eribulin Mesylate (Halaven) is considered medically necessary in the treatment of individuals with locally recurrent or metastatic breast cancer and locally recurrent or metastatic HER2+ breast cancer. Reference added. Added HCPCS codes S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. Medical Director review 9/2016. (lpr)

5/26/17 Added the following statement to “When Covered” section: “Use of Eribulin Mesylate (Halaven) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR** In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached”. Under “When Not Covered” section, added the statement “Eribulin Mesylate (Halaven) is considered investigational when used for: 1)Non-cancer indications; **OR** 2) When criteria are not met regarding FDA labeling **OR** strong endorsement/ support by nationally recognized compendia, as stated under “When Eribulin Mesylate (Halaven) is covered.” Added the following statements under “Policy Guidelines” section: 1)Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services.” 2) Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia. Medical director review 3/2017. Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)

5/11/18 Added the following to “When Covered” section: “Eribulin Mesylate (Halaven) is considered medically necessary in the treatment of individuals with unresectable or metastatic liposarcoma following at least two prior systemic therapy regimens for advanced disease, including one with an anthracycline (unless contraindicated).” Updated “Description of Procedure or Service” section to include description of mechanism of action for clarity. References added. Specialty Matched Consultant Advisory Panel review 4/25/2018. Medical Director review 5/2018. (krc)

4/30/19 Specialty Matched Consultant Advisory Panel review 4/17/2019. No change to policy statement. (krc)

Eribulin Mesylate (Halaven[®])

6/9/20 Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statements. (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.