

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Halaven (eribulin mesylate)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Halaven (eribulin mesylate)

### APPROVAL CRITERIA

Requests for Halaven (eribulin mesylate) may be approved if the following criteria are met:

- I. Individual has a diagnosis of locally recurrent or metastatic breast cancer; **AND**
  - II. Individual is using as monotherapy; **AND**
  - III. Individual is using as a single line of therapy; **AND**
  - IV. Individual has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease;
- OR**
- V. Individual has a diagnosis of locally recurrent or metastatic HER2 positive breast cancer (NCCN 2A); **AND**
  - VI. Individual is using in combination with trastuzumab (or trastuzumab biosimilars); **AND**
  - VII. Individual has symptomatic visceral disease;
- OR**
- VIII. Individual has either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease;
- OR**
- IX. Individual has a diagnosis of locally recurrent or metastatic soft tissue sarcoma (Label, NCCN 1, 2A); **AND**
  - X. Individual is using as monotherapy; **AND**
  - XI. Individual is using as a single line of therapy; **AND**
  - XII. Individual has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease.

Requests for Halaven (eribulin mesylate) may not be approved for the following criteria:

- I. Individual has a diagnosis of head and neck cancer; **OR**
- II. Individual has a diagnosis of non-small cell lung cancer; **OR**

CRX-ALL-0548-20

PAGE 1 of 2 04/24/2020

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
<b>Applicable</b>	X	X	X	X	X	X	X

III. When the above criteria are not met and for all other indications.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 28, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 28, 2020.
  - a. Breast Cancer. V1.2020. Revised January 15, 2020.
  - b. Soft Tissue Sarcoma. V5.2019. Revised January 23, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.