

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Halaven (eribulin mesylate)

CG-DRUG-70

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Halaven (eribulin mesylate)

APPROVAL CRITERIA

Requests for Halaven (eribulin mesylate) may be approved in the treatment of an individual with locally recurrent or metastatic breast cancer when all of the following criteria are met:

- I. Used as a single agent; **AND**
- II. Used in a single line of therapy; **AND**
- III. Individual has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease.

Requests for Halaven (eribulin mesylate) may be approved in the treatment of an individual with locally recurrent or metastatic HER2+ breast cancer when the following criteria are met:

- I. Used in combination with trastuzumab; **AND**
- II. Symptomatic visceral disease; **OR**
- III. Either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease.

Requests for Halaven (eribulin mesylate) may be approved in the treatment of an individual with locally recurrent or metastatic soft tissue sarcoma when all of the following criteria are met:

- I. Used as a single agent; **AND**
- II. Used in a single line of therapy; **AND**
- III. Individual has previously received at least 2 chemotherapeutic regimens for locally recurrent or metastatic disease.

Requests for Halaven (eribulin mesylate) may **not** be approved when the above criteria are not met and for all other indications, including but not limited to:

- I. Head and neck cancer
- II. Non-small cell lung cancer

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.

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Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Eribulin mesylate. In: DrugPoints® System (electronic version. Truven Health Analytics, Greenwood Village, CO. Updated October 24, 2017. Available at: <https://www.micromedexsolutions.com>. Accessed on October 27, 2017.

Eribulin mesylate Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised October 31, 2011. Accessed on October 27, 2017.

Halaven® [Product Information]. Eisai Incorporated, Woodcliff Lake, NJ; October 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201532s016lbl.pdf. Accessed on October 27, 2017.

National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on October 27, 2017.

NCCN Clinical Practice Guidelines in Oncology®. © 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on October 27, 2017.

- Breast Cancer (V2.2017). Revised April 6, 2017.
- Soft Tissue Sarcoma (V2.2017). Revised February 8, 2017.
- Uterine Neoplasms (V1.2018). Revised October 13, 2017.

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