BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.076

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 18, 2016
Subject:	Halaven	**Page:**	1 of 5

Last Review Date: June 13, 2024

Halaven

Description

Halaven (eribulin mesylate)

Background
Halaven (eribulin mesylate) is a non-taxane microtubule inhibitor used for the treatment of patients with metastatic breast cancer or unresectable or metastatic liposarcoma. Halaven inhibits the growth phase of the microtubule by inhibiting formation of mitotic spindles causing mitotic blockage and arresting the cell cycle at the G_2/M phase, which ultimately leads to apoptotic cell death. In addition, Halaven treatment of human breast cancer cells caused changes in morphology and gene expression as well as decreased migration and invasiveness in vitro (1).

Regulatory Status
FDA-approved indications: Halaven is a microtubule inhibitor indicated for the treatment of patients with: (1)

1. Metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.
2. Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Halaven label includes warnings citing the risk for neutropenia, peripheral neuropathy, embryo-fetal toxicity, and QT prolongation (1).

ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradyarrhythmias, taking drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics, and with electrolyte abnormalities. Correct hypokalemia or hypomagnesemia prior to initiating Halaven and monitor these electrolytes periodically during therapy. Avoid Halaven in patients with congenital long QT syndrome (1).

Assess for peripheral neuropathy and obtain complete blood cell counts prior to each dose. Do not administer Halaven if ANC < 1,000/mm3, platelets < 75,000/mm3 and/or in the presence of grade 3 or 4 non-hematological toxicities (1).

Halaven can cause fetal harm when administered to a pregnant woman. Advise female patients of reproductive potential to use effective contraception during treatment with Halaven and for at least 2 weeks following the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Halaven and for 3.5 months following the final dose (1).

Halaven was not studied in patients with severe hepatic impairment (Child-Pugh C) (1).

The safety and effectiveness of Halaven in patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Halaven may be considered **medically necessary** if the conditions indicated below are met.

Halaven may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic breast cancer
    a. Previously treated with at least two chemotherapy regimens including an anthracycline and taxane
2. Unresectable or metastatic liposarcoma
    a. Previously treated with an anthracycline-containing regimen

AND NONE of the following:

1. Severe hepatic impairment (Child-Pugh C)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic breast cancer
2. Unresectable or metastatic liposarcoma

AND NONE of the following:

1. Severe hepatic impairment (Child-Pugh C)
2. Disease progression or unacceptable toxicity

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Halaven (eribulin mesylate) is a non-taxane microtubule inhibitor used for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease; and for the treatment of unresectable or metastatic liposarcoma in patients who have received a prior anthracycline-containing regimen. Halaven label includes warnings for the risk for neutropenia, peripheral neuropathy, embryo-fetal toxicity, and QT prolongation. Halaven was not studied in patients with severe hepatic impairment. Halaven can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Halaven in patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Halaven while maintaining optimal therapeutic outcomes.

References

1. Halaven [package insert]. Woodcliff Lake, NJ; Eisai Inc.; September 2022.
2. NCCN Drugs & Biologics Compendium® Eribulin 2024. National Comprehensive Cancer Network, Inc. Accessed on May 1, 2024.

Policy History

Date	Action
March 2016	Addition to PA
June 2016	Annual review
June 2017	Annual editorial review and reference update Addition of age limit to renewal criteria
June 2018	Annual editorial review
June 2019	Annual review and reference update
December 2019	Annual review
March 2020	Annual review
June 2020	Annual review
September 2020	Annual review
June 2021	Annual editorial review and reference update
June 2022	Annual review and reference update
June 2023	Annual review and reference updated. Changed policy number to 5.21.076
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.