BlueCross BlueShield Federal Employee Program

HALAVEN
(eribulin mesylate)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 January 24, 2025.