Halaven

Description

Halaven (eribulin mesylate)

Background
Halaven is a prescription medicine used to treat patients with metastatic breast cancer, who have already received at least 2 other types of anticancer medicines for their breast cancer once it has spread to other parts of the body. Previous therapy should have included an anthracycline and a taxane for either early or advanced breast cancer. Halaven is also used to treat patients with liposarcoma that cannot be treated with surgery or has spread to other parts of the body, and who have received treatment with an anthracycline-containing regimen. Halaven works by limiting the growth of cancer cells, and ultimately killing them (1).

Regulatory Status
FDA-approved indication: 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.

ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics, and 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 was not studied in patients with severe hepatic impairment (Child-Pugh C) (1).

The safety and effectiveness of Halaven have not been established in pediatric patients (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** for patients 18 years of age or older for the treatment of metastatic breast cancer or unresectable or metastatic liposarcoma and if the conditions indicated below are met.

Halaven is considered **investigational** for patients below 18 years of age and 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 is a microtubule inhibitor indicated for the treatment of patients with 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. It is also indicated for unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen (1).
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Halaven while maintaining optimal therapeutic outcomes.

References

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Keywords
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.