

**POLICY:** Oncology – Halaven® (eribulin mesylate injection for intravenous use – Eisai Inc.)

**APPROVAL DATE:** 02/20/2019; selected revision 09/11/2019

### OVERVIEW

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.<sup>1</sup> Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. Halaven is also indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

### Guidelines

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 3.2019 – September 6, 2019) lists Halaven as one of the preferred single-agent regimens for patients with human epidermal growth factor receptor-2 (HER2)-negative recurrent or metastatic breast cancer.<sup>2,3</sup> It can also be used in HER2-positive disease when used in combination with Herceptin (trastuzumab for intravenous use) for recurrent or metastatic disease.

The NCCN soft tissue sarcoma guidelines (version 3.2019 – August 16, 2019) lists Halaven as a single-agent therapy (most are category 2A) for a variety of subtypes with non-specific histologies.<sup>3</sup> For liposarcoma, Halaven is a category 1 recommended agent. The NCCN compendium<sup>2</sup> recommends Halaven for the following soft tissue sarcoma subtypes: extremity/superficial trunk, head/neck, retroperitoneal/intra-abdominal, angiosarcoma, and pleomorphic rhabdomyosarcoma. Halaven is a category 2B recommended therapy for uterine sarcoma.

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Halaven. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing for the indication. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Halaven as well as the monitoring required for adverse events and long-term efficacy, approval requires Halaven to be prescribed by or in consultation with a prescriber who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Halaven is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

---

1. **Breast Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) The patient has metastatic disease; AND
  - B) The patient has been previously treated with at least two chemotherapy regimens.  
Note: Examples of chemotherapy include doxorubicin, epirubicin, paclitaxel, docetaxel, Abraxane [albumin-bound paclitaxel]; AND
  - C) The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to 1.4 mg/m<sup>2</sup> administered intravenously on Days 1 and 8 of a 21-day cycle.

- 
2. **Soft Tissue Sarcoma of the Extremity/Superficial Trunk, Head/Neck, Retroperitoneal/Intra-Abdominal, Angiosarcoma, Pleomorphic Rhabdomyosarcoma, and Liposarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
    - A) The patient has unresectable, progressive, or metastatic disease; AND
    - B) The patient has been treated with at least one prior anthracycline-containing chemotherapy regimen.  
Note: Examples of chemotherapy regimens include doxorubicin and dacarbazine, doxorubicin with ifosfamide and mesna, epirubicin with ifosfamide and mesna; AND
    - C) The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to 1.4 mg/m<sup>2</sup> administered intravenously on Days 1 and 8 of a 21-day cycle.

---

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

## REFERENCES

1. Halaven® Intravenous Infusion [prescribing information]. Woodcliff Lake, NJ: Eisai Inc.; October 2016.
2. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on September 9, 2019. Search term: eribulin mesylate.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – September 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on September 9, 2019.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 3.2019 – August 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on September 9, 2019.

## HISTORY

Type of Revision	Summary of Changes	Approval Date
New policy	--	11/21/2018
Early annual revision	Added criteria for soft tissue sarcoma requiring patient has tried at least one prior chemotherapy regimen. Changed metastatic breast cancer to “metastatic disease” and changed chemotherapy agents to chemotherapy “regimens” for consistency with other policies. Changed dosing to “up to” a maximum dose instead of individual doses.	02/20/2019
Selected revision	According to new formatting changes, moved examples of chemotherapies to “Note”. Deleted “Other Cancer-Related Indications” to be consistent with prior authorization format.	09/11/2019