PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Halaven Prior Authorization Policy
- Halaven® (eribulin mesylate intravenous infusion– Eisai)

REVIEW DATE: 03/16/2022

OVERVIEW

Halaven, a microtubule inhibitor, is indicated for the following uses:[1]

- **Breast cancer**, metastatic, in patients 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.
- **Liposarcoma,** for the treatment of patients with unresectable or metastatic disease who have received a prior anthracycline-containing regimen.

Guidelines

Halaven has been addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2-5]

- **Breast Cancer:** Guidelines (version 2.2022 – December 20, 2021) list 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.[2] Halaven, in combination with trastuzumab or Margenza® (margetuximab-cmkb intravenous infusion) is also recommended for the treatment of recurrent or metastatic HER2-positive disease. Both of these are category 2A recommendations.
- **Soft Tissue Sarcoma:** Guidelines (version 3.2021 – January 26, 2021) list Halaven as a subsequent line of treatment of advanced or metastatic soft tissue sarcoma.[3] Halaven is a category 1 recommendation for liposarcoma and category 2A for other subtypes. The NCCN compendium recommends Halaven for the following soft tissue sarcoma subtypes: extremity/body wall, head/neck, retroperitoneal/intra-abdominal, angiosarcoma, solitary fibrous tumor, and pleomorphic rhabdomyosarcoma.[4]
- **Uterine Neoplasms:** Guidelines (version 1.2022 – November 4, 2021) list Halaven as a recommended treatment regimen for the treatment of patients with recurrent or metastatic uterine sarcoma that has progressed on prior cytotoxic chemotherapy (category 2B).[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Halaven. 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, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has been previously treated with at least two chemotherapy regimens; AND
     Note: Examples of chemotherapy regimens include doxorubicin, epirubicin, paclitaxel, docetaxel, Abraxane (albumin-bound paclitaxel intravenous infusion).
   - **D)** The medication is prescribed by or in consultation with an oncologist.

2. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable, progressive, or advanced/metastatic disease; AND
   - **C)** Patient has been treated with at least one prior anthracycline-containing chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens include doxorubicin and dacarbazine, doxorubicin with ifosfamide and mesna, epirubicin with ifosfamide and mesna.
   - **D)** Patient has ONE of the following subtypes (i, ii, iii, iv, v, vi, or vii):
     - **i.** Angiosarcoma; OR
     - **ii.** Liposarcoma; OR
     - **iii.** Pleomorphic rhabdomyosarcoma; OR
     - **iv.** Retroperitoneal/intra-abdominal soft tissue sarcoma; OR
     - **v.** Soft tissue sarcoma of the extremity/body wall; OR
     - **vi.** Soft tissue sarcoma of the head/neck; OR
     - **vii.** Solitary fibrous tumor; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

3. **Uterine Sarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has been treated with at least one prior chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine, epirubicin.
   - **D)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Halaven is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Halaven® intravenous infusion [prescribing information]. Nutley, NJ: Eisai; December 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2022.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2021 – January 26, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2022.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2022. Search term: eribulin mesylate.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – November 4, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2022.