PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/20/2024

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 unresectable or metastatic disease in patients 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 2.2024 – March 11, 2024) 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 (fourth line and beyond) for the treatment of recurrent or metastatic HER2-positive disease. Both of these are category 2A recommendations.
- **Soft Tissue Sarcoma:** Guidelines (version 3.2023 – December 12, 2023) 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, solitary fibrous tumor, and pleomorphic rhabdomyosarcoma.[4]
- **Uterine Neoplasms:** Guidelines (version 2.2024 – March 6, 2024) list Halaven under "other recommended regimens" as second-line or subsequent therapy for the treatment of patients with recurrent or metastatic uterine sarcoma (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 ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has human epidermal growth factor receptor 2 (HER2)-negative and hormone-receptor (HR)-positive disease and meets ONE of the following (a, b, or c):
       - **a)** The medication will be used in the first-line setting and the tumor has no germline *BRCA* mutation; OR
       - **b)** The medication will be used second-line because the patient is not a candidate for Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy; OR
       - **c)** The medication will be used after at least two prior chemotherapy regimens; OR
         Note: Examples of chemotherapy regimens include doxorubicin, epirubicin, paclitaxel, docetaxel, Abraxane (albumin-bound paclitaxel intravenous infusion).
     - **ii.** Patient has triple-negative breast cancer and meets one of the following (a or b):
       - **a)** The medication will be used in the first-line setting if the programmed death ligand-1 (PD-L1) combined positive score (CPS) < 10 and there is no germline *BRCA* mutation; OR
       - **b)** The medication is used as subsequent therapy (second-line or beyond); OR
     - **iii.** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease and meets both of the following (a and b):
       - **a)** The medication will be used in fourth-line therapy or beyond; AND
       - **b)** The medication will be used in combination with Margenza (margetuximab-cmkb intravenous infusion) or trastuzumab; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

2. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets ALL of the following (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, or v):
     - **i.** Liposarcoma; OR
     - **ii.** Pleomorphic rhabdomyosarcoma; OR
     - **iii.** Retroperitoneal/intra-abdominal soft tissue sarcoma; OR
     - **iv.** Soft tissue sarcoma of the extremity/body wall; OR
     - **v.** Soft tissue sarcoma of the head/neck; 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 ALL of the following (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; September 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2023 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024. Search term: eribulin.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – March 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2024.