CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Microtubule Inhibitor) – Halaven Utilization Management Medical Policy
- Halaven® (eribulin mesylate intravenous infusion – Eisai)

REVIEW DATE: 03/05/2025

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.[1] 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 1.2025 – January 31, 2025) 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 4.2024 – November 21, 2024) 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 2.2025 – January 31, 2025) 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 medical benefit coverage of Halaven. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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.

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RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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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.

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

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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.

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

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Other Uses with Supportive Evidence

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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.

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

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 1.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2025.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2025.
4. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 5, 2025. Search term: eribulin.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2025.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Cancer:** The following new criteria were added based on NCCN guideline recommendations: • In patients with human epidermal growth factor receptor 2 (HER2)-negative and hormone-receptor (HR)-positive disease, for use of Halaven in the first-line setting the tumor should not have germline BRCA mutation; or for use in the second-line setting, the medication can be used if the patient is not a candidate for Enhertu therapy. Previous criteria remains for use of Halaven after at least two prior chemotherapy regimens. • In triple-negative breast cancer, the medication will be used in the first-line setting if the tumor has no germline BRCA mutation and the programmed death ligand-1 (PD-L1) combined positive score (CPS) is less than 10. Criteria for Halaven use as subsequent therapy was also added. • In HER2-positive disease, criteria were added for Halaven use as fourth-line therapy or beyond and for its use in combination with Margenza (margetuximab-cmkb intravenous infusion) or trastuzumab. **Soft Tissue Sarcoma:** Deleted angiosarcoma and solitary fibrous tumor from list of subtypes since it's no longer recommended in NCCN guidelines.	03/22/2023
Annual Revision	No criteria changes.	03/20/2024
Annual Revision	No criteria changes.	03/05/2025
Update	04/21/2025: The policy name was changed from "Oncology (Injectable) – Halaven UM Medical Policy" to "Oncology (Injectable – Microtubule Inhibitor) – Halaven UM Medical Policy".	N/A

N/A – Not applicable.

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