Reference number(s)
1893-A

SPECIALTY GUIDELINE MANAGEMENT

HALAVEN (eribulin mesylate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Halaven is 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.
2. Halaven is indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

B. Compendial Uses
1. Breast cancer
2. Soft tissue sarcoma
   a. Retroperitoneal/intra-abdominal soft tissue sarcoma
   b. Pleomorphic rhabdomyosarcoma
   c. Extremity/body wall, head/neck

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status testing results (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer
Authorization of 12 months may be granted for treatment of recurrent or metastatic breast cancer or breast cancer with no response to preoperative systemic therapy when any of the following criteria is met:
1. The requested medication will be used as a single agent for HER2-negative disease; or
2. The requested medication will be used in combination with margetuximab-cmkb or trastuzumab for HER2-positive disease.

B. Soft Tissue Sarcoma
Authorization of 12 months may be granted for treatment of any of the following types of soft tissue sarcoma, as single-agent therapy:
1. Liposarcoma
2. Pleomorphic rhabdomyosarcoma
3. Retroperitoneal/intra-abdominal soft tissue sarcoma

4. Extremity/ body wall, head/neck

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Halaven [package insert]. Nutley, NJ: Eisai Inc.; September 2022.
2. The NCCN Drugs & Biologics Compendium 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 6, 2022.