

## 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
  - a. Human epidermal growth factor receptor (HER2)-negative recurrent or metastatic breast cancer
  - b. HER2-positive recurrent or metastatic breast cancer
2. Soft tissue sarcoma
  - a. Angiosarcoma
  - b. Retroperitoneal/intra-abdominal
  - c. Rhabdomyosarcoma
  - d. Extremities, superficial trunk or head and neck

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Breast Cancer**

Authorization of 12 months may be granted for treatment of breast cancer.

###### B. **Soft Tissue Sarcoma**

Authorization of 12 months may be granted for treatment of any of the following types of soft tissue sarcoma:

1. Liposarcoma
2. Angiosarcoma
3. Rhabdomyosarcoma
4. Retroperitoneal/intra-abdominal soft tissue sarcoma
5. Extremities, superficial trunk or head and neck soft tissue sarcoma

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Halaven [package insert]. Woodcliff Lake, NJ: Eisai Inc.; October 2016.

Reference number(s)
1893-A

- 2. The NCCN Drugs & Biologics Compendium™ © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed January 9, 2017.