Eribulin Mesylate (Halaven®)

NDC CODE(S) 62856-0389-XX HALAVEN 1MG/2ML Solution (EISAI)

DESCRIPTION

Eribulin mesylate is a synthetic analog of halichondrin B, a product isolated from the marine sponge *Halichondria okadai.* A microtubule dynamics inhibitor, eribulin mesylate prevents the growth phase of microtubules without affecting the shortening phase. Its effects are exerted via a tubulin-based antimitotic mechanism which leads to cell-cycle block, disruption of mitotic spindles and ultimately, apoptotic cell death after prolonged mitotic blockage.

POLICY

- Eribulin mesylate for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met: **(See Medical Appropriateness below.)**
  - Breast cancer
  - Liposarcoma
  - Soft tissue sarcoma
- Eribulin mesylate for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

Patient is at least 18 years of age; **AND**

Breast Cancer

- Patient has metastatic disease; **AND**
  - Used as a single agent for patients who have previously received at least two chemotherapy regimens for the treatment of metastatic disease; **AND**
  - Prior therapy includes treatment with an anthracycline and a taxane in either the adjuvant or metastatic setting; **OR**
- Patient has recurrent or metastatic disease; **AND**
  - Used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease and one of the following:
    - Disease is hormone receptor negative; **OR**
    - Disease is hormone receptor positive with visceral crisis or refractory to endocrine therapy; **OR**
  - Used in combination with trastuzumab for HER2-positive disease

Liposarcoma

- Used as a single agent; **AND**
- Patient has unresectable or metastatic or recurrent disease; **AND**
- Patient has received prior anthracycline-based therapy (e.g. doxorubicin, etc.)

Soft Tissue Sarcoma

- Used as a single agent; **AND**
- Patient has been diagnosed with one of the following sub-types of STS:
  - Angiosarcoma; **AND**

- Used as palliative therapy
- Pleomorphic Rhabdomyosarcoma; **AND**
  - Used as subsequent therapy for advanced or metastatic disease
- Retroperitoneal/Intra-abdominal; **AND**
  - Used as palliative subsequent therapy for recurrent unresectable or stage IV disease
- Extremity/Body Wall, Head/Neck; **AND**
  - Used as palliative subsequent therapy for advanced or metastatic disease with disseminated metastases
- Solitary Fibrous Tumor

RENEWAL CRITERIA

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe QT-prolongation, severe neutropenia (ANC < 500/mm^3), peripheral neuropathy, etc.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
All Indications	Administer 1.4 mg/m^2, intravenously, on days 1 and 8, repeated every 21 days until disease progression or unacceptable toxicity

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 80 billable units every 21 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Halaven [package insert]. Woodcliff Lake, NJ; Eisai Inc; December 2017. Accessed February 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) eribulin. National Comprehensive Cancer Network, 20210. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2021.
3. Cortes J, O'Shaughnessy J, Loesch D, et al; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) investigators. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. Lancet. 2011;377(9769):914-923.
4. Schöffski P, Chawla S, Maki RG, et al. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomised, open-label, multicentre, phase 3 trial. Lancet. 2016;387(10028):1629-1637.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma Version 2.2020. National Comprehensive Cancer Network, 20201. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed February 2021.
6. Schöffski P, Ray-Coquard IL, Cioffi A, et al. Activity of eribulin mesylate in patients with soft-tissue sarcoma: a phase 2 study in four independent histological subtypes. Lancet Oncol. 2011;12(11):1045-1052.
7. Lexi-Comp Online. (2020, March). AHFS DI. *Eribulin mesylate*. Retrieved March 5, 2021 from Lexi-Comp Online with AHFS.
8. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2021, February). *Eribulin*. Retrieved March 5, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 6/30/2021

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