

## Halaven® (eribulin) (Intravenous)

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### I. Length of Authorization

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

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Halaven 1 mg/2 mL solution for injection: 8 vials every 21 days

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

- 80 billable units every 21 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**  
**Breast Cancer †<sup>1-3</sup>**
- 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 †<sup>1,4</sup>**

- 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 (STS) ‡<sup>2,5,6</sup> ◊**

- 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ◊ Orphan Drug

## **IV. Renewal Criteria<sup>1</sup>**

Coverage can be renewed based on the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **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<sup>3</sup>), peripheral neuropathy, etc.

## V. Dosage/Administration <sup>1,6</sup>

| Indication      | Dose   |
|-----------------|--|
| All Indications | Administer 1.4 mg/m <sup>2</sup> , intravenously, on days 1 and 8, repeated every 21 days until disease progression or unacceptable toxicity |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9179 – Injection, eribulin mesylate, 0.1 mg; 1 billable unit = 0.1mg

### NDC:

- Halaven 1 mg/2 mL solution for injection: 62856-0389-xx

## VII. References

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, 2021. 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, 2021. 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.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10  | ICD-10 Description   |
|---------|--|
| C22.3   | Angiosarcoma of liver  |
| C47.0   | Malignant neoplasm of peripheral nerves of head, face and neck                                 |
| C47.10  | Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder          |
| C47.11  | Malignant neoplasm of peripheral nerves of right upper limb, including shoulder                |
| C47.12  | Malignant neoplasm of peripheral nerves of left upper limb, including shoulder                 |
| C47.20  | Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip               |
| C47.21  | Malignant neoplasm of peripheral nerves of right lower limb, including hip                     |
| C47.22  | Malignant neoplasm of peripheral nerves of left lower limb, including hip                      |
| C47.3   | Malignant neoplasm of peripheral nerves of thorax  |
| C47.4   | Malignant neoplasm of peripheral nerves of abdomen   |
| C47.5   | Malignant neoplasm of peripheral nerves of pelvis  |
| C47.6   | Malignant neoplasm of peripheral nerves of trunk, unspecified                                  |
| C47.8   | Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system      |
| C47.9   | Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified              |
| C48.0   | Malignant neoplasm of retroperitoneum  |
| C48.1   | Malignant neoplasm of specified parts of peritoneum  |
| C48.2   | Malignant neoplasm of peritoneum, unspecified  |
| C48.8   | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum                      |
| C49.0   | Malignant neoplasm of connective and soft tissue of head, face and neck                        |
| C49.10  | Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder |
| C49.11  | Malignant neoplasm of connective and soft tissue of right upper limb                           |
| C49.12  | Malignant neoplasm of connective and soft tissue of left lower limb                            |
| C49.20  | Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip      |
| C49.21  | Malignant neoplasm of connective and soft tissue of right lower limb                           |
| C49.22  | Malignant neoplasm of connective and soft tissue of left lower limb                            |
| C49.3   | Malignant neoplasm of connective and soft tissue of thorax                                     |
| C49.4   | Malignant neoplasm of connective and soft tissue of abdomen                                    |
| C49.5   | Malignant neoplasm of connective and soft tissue of pelvis                                     |
| C49.6   | Malignant neoplasm of connective and soft tissue of trunk, unspecified                         |
| C49.8   | Malignant neoplasm of overlapping sites of connective and soft tissue                          |
| C49.9   | Malignant neoplasm of connective and soft tissue, unspecified                                  |
| C50.011 | Malignant neoplasm of nipple and areola, right female breast                                   |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast                                    |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast                             |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast                                     |

| ICD-10  | ICD-10 Description  |
|---------|---|
| C50.022 | Malignant neoplasm of nipple and areola, left male breast               |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast        |
| C50.111 | Malignant neoplasm of central portion of right female breast            |
| C50.112 | Malignant neoplasm of central portion of left female breast             |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast      |
| C50.121 | Malignant neoplasm of central portion of right male breast              |
| C50.122 | Malignant neoplasm of central portion of left male breast               |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast        |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast       |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast        |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast         |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast          |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast   |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast       |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast        |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast         |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast          |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast   |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast       |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast        |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast         |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast          |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast   |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast       |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast        |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast         |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast          |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast   |
| C50.611 | Malignant neoplasm of axillary tail of right female breast              |
| C50.612 | Malignant neoplasm of axillary tail of left female breast               |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast        |
| C50.621 | Malignant neoplasm of axillary tail of right male breast                |

| ICD-10  | ICD-10 Description   |
|---------|--|
| C50.622 | Malignant neoplasm of axillary tail of left male breast              |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast       |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast       |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast        |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast         |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast          |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast   |
| C50.911 | Malignant neoplasm of unspecified site of right female breast        |
| C50.912 | Malignant neoplasm of unspecified site of left female breast         |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast  |
| C50.921 | Malignant neoplasm of unspecified site of right male breast          |
| C50.922 | Malignant neoplasm of unspecified site of left male breast           |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast    |
| Z85.831 | Personal history of malignant neoplasm of soft tissue                |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |  |   |
|---|--|---|
| Jurisdiction  | Applicable State/US Territory          | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI               | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO                         | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL                             | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM             | Novitas Solutions, Inc.                           |
| 8   | MI, IN                                 | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI                             | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL                             | Palmetto GBA, LLC                                 |

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory   | Contractor                               |
|--------------|---|--|
| M (11)       | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                        |
| L (12)       | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                  |
| K (13 & 14)  | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS) |
| 15           | KY, OH  | CGS Administrators, LLC                  |