

# 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 in a single-dose vial 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 † ‡ 1-3

- 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 unresectable or metastatic disease OR inflammatory disease that has not responded to preoperative systemic therapy ‡; AND
  - Patient has HER2-negative disease; AND
    - Used as a single agent; **AND**



- Patient has hormone receptor-positive disease with visceral crisis or is endocrine therapy refractory; **AND**
- Used in one of the following treatment settings:
  - First-line therapy if no germline BRCA 1/2 mutation
  - Second-line therapy if not a candidate for fam-trastuzumab-nxki
  - Third-line therapy and beyond; OR
- Patient has triple negative breast cancer (TNBC); AND
  - Used as a single agent; AND
  - Used in one of the following treatment settings:
    - First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation
    - Subsequent therapy; **OR**
- o Patient has HER2-positive disease; AND
  - Used as fourth-line therapy and beyond in combination with margetuximab-cmkb
     OR trastuzumab

#### Liposarcoma † 1,4

- 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) ‡Φ <sup>2,5,6</sup>

- Used as a single agent; AND
- Patient has been diagnosed with one of the following sub-types of STS:
  - o 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
  - o Extremity/Body Wall, Head/Neck; AND
    - Used as palliative subsequent therapy for advanced or metastatic disease with disseminated metastases
- † FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

#### IV. Renewal Criteria 1

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: QT-prolongation, severe neutropenia (ANC < 500/mm<sup>3</sup>), peripheral neuropathy (Grade 3 or 4), etc.

#### Dosage/Administration 1,6 V.

Indication	Dose
All Indications	Administer 1.4 mg/m², 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
- Halaven 1 mg/2 mL solution in a single-dose vial for injection: 62856-0389-xx

#### VII. References

- 1. Halaven [package insert]. Woodcliff Lake, NJ; Eisai Inc; December 2021. Accessed January
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) eribulin. National Comprehensive Cancer Network, 2023. 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 January 2023.
- 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 2.2021. National Comprehensive Cancer Network, 2023. 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 January 2023.
- 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	
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	

ICD-10	ICD-10 Description	
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	
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	



ICD-10	ICD-10 Description	
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	
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	

# 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: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. 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		



Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
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		
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		



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If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <a href="https://ocrportal.hhs.gov/ocr/portal/lobby.jsf">https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</a>, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <a href="http://www.hhs.gov/ocr/office/file/index.html">http://www.hhs.gov/ocr/office/file/index.html</a>.

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ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).
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You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

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(መስጣት ለተሳናቸው: 763.847.4013 ).
ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နမၤန္ရ၊ ကျို်အတါမၤစၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္၌လီ၊. ကိႏ 1.800.940.5049 (TTY: 763.847.4013).
ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។
         ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).
ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).
주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1,800,940,5049 (TTY: 763,847,4013), 번으로 전화해 주십시오.
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PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa

1.800.940.5049 (TTY: 763.847.4013).