Medical Policy:

Halaven™ (eribulin) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.84	April 3, 2025	

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

80 billable units every 21 days

Dosing and Administration

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

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 or older; **AND**

1**. Breast Cancer †**

A. Patient has metastatic disease; **AND**

i. Used as a single agent for patients who have previously received at least **TWO** chemotherapy regimens for the treatment of metastatic disease; **AND**

ii. Prior therapy includes treatment with an anthracycline and a taxane in either the adjuvant or metastatic setting; **OR**

B. Patient has recurrent unresectable or metastatic disease **OR** inflammatory disease that has not responded to preoperative systemic therapy ‡; **AND**

iii. Patient has HER2-negative disease; **AND**

a. Used as a single agent**; AND**

b. Patient has hormone receptor-positive disease with visceral crisis or is endocrine therapy refractory; **AND**

c. Used in **ONE** of the following treatment settings:

1) First-line therapy if no germline BRCA 1/2 mutation

2) Second-line therapy if not a candidate for fam-trastuzumab-nxki

3) Third-line therapy and beyond; **OR**

iv. Patient has triple negative breast cancer (TNBC); **AND**

a. Used as a single agent; **AND**

b. Used in **ONE** of the following treatment settings:

1) First-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation

2) Subsequent therapy; **OR**

v. Patient has HER2-positive disease; **AND**

a. Used as fourth-line therapy and beyond in combination with margetuximab-cmkb **OR** trastuzumab

2**. Liposarcoma †**

A. Patient has unresectable or metastatic or recurrent disease; **AND**

B. Patient received prior anthracycline-based therapy; **AND**

C. Must be used as a single agent

3. **Soft tissue sarcoma**

A. Used as a single agent for palliative therapy; **AND**

B. Patient has been diagnosed with one of the following sub-types of STS:

i. Pleomorphic Rhabdomyosarcoma; **AND**

a. Used as subsequent therapy for advanced or metastatic disease

ii. Retroperitoneal/Intra-Abdominal; **AND**

a. Used as alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable or stage IV disease; **OR**

b. Used as palliative subsequent therapy for recurrent unresectable or stage IV disease

iii. Extremity/Body Wall, Head/Neck; **AND**

a. Used as palliative subsequent therapy for advanced or metastatic disease with disseminated metastases

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

II. Renewal Criteria

Authorizations can be renewed based on the following criteria:

1. Patient continues to meet criteria identified above; **AND**
2. Disease response as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT-prolongation, severe neutropenia (ANC < 500/m^3), peripheral neuropathy; etc.

Limitations/Exclusions

Halaven is considered investigational when used for any indication not listed above.

Applicable Procedure Codes

Code	Description
J9179	Injection, eribulin mesylate, 0.1 mg; 1 billable unit = 0.1mg

Applicable NDCs

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

ICD-10 Diagnoses

Code	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
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

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
Z85.3	Personal history of malignant neoplasm of breast
Z85.831	Personal history of malignant neoplasm of soft tissue

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/03/2025	Annual Review: Initial Criteria: Soft tissue sarcoma: Added: “for palliative therapy” to the phrase: “Used as a single agent for palliative therapy; AND” To heading regarding: Retroperitoneal/Intra-Abdominal; AND Added “Used as alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable or stage IV disease; OR”
EmblemHealth & ConnectiCare	2/29/2024	Annual Review: Removed package insert link, added dosing chart. Initial Criteria: Breast Cancer Removed: “Patient has hormone receptor-negative disease; OR” Added: “Used in one of the following treatment settings: 1) First-line therapy if no germline BRCA 1/2 mutation 2) Second-line therapy if not a candidate for fam-trastuzumab-nxki 3) 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” Modified the following statement: “Patient has HER2-positive disease; AND Used as fourth-line therapy and beyond in combination with margetuximab-cmkb OR trastuzumab “ Previously was: “Used in combination with margetuximab-cmkb OR trastuzumab for HER2-positive disease; AND Used as third-line therapy and beyond”

		Soft tissue sarcoma: Removed :Angiosarcoma; AND Used as palliative therapy and Solitary Fibrous Tumor"
EmblemHealth & ConnectiCare	6/28/2023	Annual Review: Breast Cancer: Initial Criteria: Removed "Used as subsequent therapy in metastatic disease for patients who have previously received therapy with an anthracycline and a taxane† ; **OR** Patient has recurrent or metastatic disease and one of the following: i. Hormone receptor negative ii. Hormone receptor positive and refractory to endocrine therapy iii. Patient has symptomatic visceral disease or visceral crisis; **AND** ▪ Used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease; **OR** ▪ Used in combination with trastuzumab for HER2-positive disease" Added "Patient has metastatic disease; **AND** o Used as a single agent for patients who have previously received at least two chemotherapy regimens for the treatment of metastatic disease; **AND** o 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** o Used as a single agent for HER2-negative disease; **AND** - Patient has hormone receptor-negative disease; **OR** - Patient has hormone receptor-positive disease with visceral crisis or is endocrine therapy refractory; **OR** o Used in combination with margetuximab-cmkb OR trastuzumab for HER2-positive disease; **AND** - Used as third-line therapy and beyond" Soft Tissue Sarcoma: Initial Criteria: Removed "Must be used as a single agent for palliative treatment; **AND** a. Patient has been diagnosed with one of the following sub-types of STS: i. Angiosarcoma ‡ ii. Pleomorphic Rhabdomyosarcoma ‡ iii. Retroperitoneal/Intra-abdominal ‡; **AND** • Used for unresectable or progressive disease iv. Extremity/Superficial Trunk, Head/Neck ‡; **AND** • Used for metastatic disease or recurrent disease with disseminated metastases Added "Used as a single agent; **AND** • Patient has been diagnosed with one of the following sub-types of STS: o Angiosarcoma; **AND** – Used as palliative therapy o Pleomorphic Rhabdomyosarcoma; **AND** – Used as subsequent therapy for advanced or metastatic disease o 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 o Solitary Fibrous Tumor"

EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	1/1/2020	Annual review

References

1. Halaven [package insert]. Woodcliff Lake, NJ; Eisai Inc; December 2017. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) eribulin. National Comprehensive Cancer Network, 2018. 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 August 2018.