Clinical Policy Title:	eribulin mesylate
Policy Number:	RxA.388
Drug(s) Applied:	Halaven®
Original Policy Date:	03/06/2020
Last Review Date:	07/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Eribulin mesylate (Halaven®) is a microtubule dynamics inhibitor. It 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.
- Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
eribulin mesylate (Halaven®)	Breast cancer	1.4 mg/m^2 intravenously over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2
	Soft tissue sarcoma (STS)	1.4 mg/m^2 intravenously over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2
	For Hepatic Impairment: Mild hepatic impairment (Child-Pugh A): Decrease starting dose to 1.1 mg/m^2 intravenously Moderate hepatic impairment (Child-Pugh B): Decrease starting dose to 0.7 mg/m^2 intravenously **For Renal Impairment:** CrCl 15 to 49 mL/min: Decrease starting dose to 1.1 mg/m^2 intravenously		

Dosage Forms

- Injection in a single-use vial: 1 mg/2 mL (0.5 mg per mL).

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the

terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is metastatic or recurrent;
5. Member must have received at least two chemotherapeutic regimen and prior therapy should have included an anthracycline and a taxane in either the adjuvant or the metastatic setting;
6. Prescribed as one of the following (a or b):
   a. As a single agent for HER2-negative disease;
   b. Third-line therapy and beyond in combination with margetuximab-cmkb or trastuzumab for recurrent unresectable (local or regional) or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive disease;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

B. Soft Tissue Sarcoma (must meet all)**:**

1. Diagnosis of one of the following soft tissue sarcoma (STS) subtypes (a, b, or c):
   a. Metastatic or recurrent extremity/superficial trunk and head/neck STS;
   b. Unresectable or progressive retroperitoneal/intra-abdominal STS;
   c. Rhabdomyosarcoma STS;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥18 years;
4. Prescribed as a single agent;
5. Member must have received a prior anthracycline-containing regimen;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Halaven® for a covered indication and has received this medication for at least one 21-day cycle;

2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 12 months

III. APPENDICES

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: Human Epidermal Growth Factor Receptor 2
NCCN: National Comprehensive Cancer Network
STS: Soft Tissue Sarcoma

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information

- There are over 50 different histologic STS subtypes. While Halaven® is only FDA-approved for the treatment of one subtype (liposarcomas), the NCCN recommends Halaven® for STS with extremity/superficial trunk, head/neck, and retroperitoneal/intraabdominal origins, as well as rhabdomyosarcoma. For all subtypes, the NCCN recommends Halaven® to be used only as palliative therapy (category 1 for liposarcoma; 2A for all other subtypes).

References

1. Halaven® Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc.; December 2021. Available at: https://halaven.com/-/media/Files/Halaven/HALAVEN-Full-Prescribing-Information.pdf?v=20211013. Accessed March 23, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed March 23, 20221.
3. National Comprehensive Cancer Network. Breast Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 23, 2022.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed March 23, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020

Policy was reviewed: 1. Policy title table was updated. 2. Initial approval criteria I.A.5 for breast cancer updated to remove HER2-positive prescribing as no longer applicable. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. Age symbols was updated. 5. Updated Appendix D to remove prescribing methods. 6. References were updated.	08/26/2020	09/14/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A.5 was updated to include new criteria I.A.5.b “Third-line therapy and beyond in combination with margetuximab-cmkb…”. 3. Initial Approval Criteria I.A was updated to include new criteria I.A.6 **“**For inflammatory breast cancer request should meet…” and I.A.6.a “As a single agent with no response to…” 4. Initial Approval Criteria I.B.1.c was updated to include “Solitary Fibrous Tumor.” 5. Continued Therapy criteria II.A.1 was rephrased to " Member is currently receiving medication that has been authorized by RxAdvance...". 6. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 7. Reference reviewed and updated.	05/31/2021	09/14/2021

Policy was reviewed: 1. Dosing Information, Dosing Regimen, Halaven®: Updated to include hepatic impairment dosing information for indication Breast cancer & STS. 2. Dosing Information, Dosing Regimen, Halaven®: Updated to include renal impairment dosing information for indication Breast cancer & STS. 3. Dosage Forms: Updated dosage form from Injection in a single-use vial: 1 mg/2 mL to Injection in a single-use vial: 1 mg/2 mL (0.5 mg per mL). 4. Initial Approval Criteria, I.A.5: Updated to include new prior therapy criteria Member must have received at least two chemotherapeutic regimen and prior therapy should have included an anthracycline and a taxane in either the adjuvant or the metastatic setting. 5. Initial Approval Criteria, I.A.6: Updated to remove prior criteria pertaining to indication Breast cancer, "For inflammatory breast cancer request should meet one of the following (a or b): a. As a single agent with no response to preoperative systemic therapy for HER2-negative disease; b. Third-line therapy and beyond in combination with margetuximab-cmkb or trastuzumab for patients with no response to preoperative systemic therapy, or recurrent unresectable (local or regional) or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive disease." 6. Initial Approval Criteria, I.B.1.c: Updated diagnostic criteria from Angiosarcoma or pleomorphic	05/02/2022	07/18/2022

rhabdomyosarcoma, Solitary Fibrous Tumor to Rhabdomyosarcoma STS. 7. Initial Approval Criteria, I.B.5: Updated to include new prior therapy criteria Member must have received a prior anthracycline-containing regimen. 8. References were reviewed and updated.		