RXADVANCE
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Clinical Policy Title:	eribulin mesylate
Policy Number:	RxA.388
Drug(s) Applied:	Halaven®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
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 IV over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2
Eribulin Mesylate (Halaven®)	STS	1.4 mg/m^2 IV over 2 to 5 minutes on days 1 and 8 of a 21-day cycle	1.4 mg/m^2

Dosage Forms

- Injection in a single-use vial: 1 mg/2 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.

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. Prescribed as a single agent for HER2-negative disease;
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
HIM: 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;
2. Angiosarcoma or pleomorphic rhabdomyosarcoma (off-label);
3. Prescribed by or in consultation with an oncologist;
4. Age > 18 years;
5. Prescribed as a single agent;
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
HIM: 6 months

II. Continued Therapy Approval

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

1. 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/m2 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
HIM: 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 angiosarcoma and pleomorphic 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 2017. Available at: http://www.halaven.com. Accessed July 12, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 12, 2020.
3. National Comprehensive Cancer Network. Breast Cancer Version 5.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Updated July 15, 2020. Accessed August 26, 2020.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Updated May 28, 2020. Accessed July 12, 2020.

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