Clinical Policy Title:	eribulin mesylate
Policy Number:	RxA.388
Drug(s) Applied:	Halaven®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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. 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

References

1. National Comprehensive Cancer Network. Breast Cancer Version 4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed April 20, 2023.
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed April 20, 2023.

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. References were updated.	08/26/2020	09/14/2020

Policy was reviewed: 1. 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…". 2. 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 3. Initial Approval Criteria I.B.1.c was updated to include "Solitary Fibrous Tumor." 4. Continued Therapy criteria II.A.1 was rephrased to " Member is currently receiving medication that has been authorized by RxAdvance...". 5. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 6. Reference reviewed and updated.	05/31/2021	09/14/2021
Policy was reviewed: 1. 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. 2. 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."	05/02/2022	07/18/2022

3. Initial Approval Criteria, I.B.1.c: Updated diagnostic criteria from Angiosarcoma or pleomorphic rhabdomyosarcoma, Solitary Fibrous Tumor to Rhabdomyosarcoma STS. 4. Initial Approval Criteria, I.B.5: Updated to include new prior therapy criteria Member must have received a prior anthracycline-containing regimen. 5. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	04/20/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023