Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PHAR.318	**Effective Date: 01/2018** **Revision Date: 10/2022**
Policy Name: Eribulin Mesylate (Halaven)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2022 annual review: removed coverage for angiosarcoma and solitary fibrous tumor as use is no longer supported by the NCCN Soft Tissue Sarcoma guidelines; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Eribulin Mesylate (Halaven)

Reference Number: PA.CP.PHAR.318
Effective Date: 01/2018
Last Review Date: 10/2022

Coding Implications
Revision Log

Description
Eribulin mesylate (Halaven®) is a microtubule dynamics inhibitor.

FDA Approved Indication(s)
Halaven 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

Policy/Criteria
It is the policy of PA Health & Wellness ® that Halaven is **medically necessary** when the following criteria are met:

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 in one of the following ways (a, b, or c):
   a. In combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease as third line therapy or beyond;
   b. In combination with Margenza™ for HER2-positive disease as third line therapy or beyond;
   c. 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)*.

Approval duration: 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. Advanced, metastatic, or recurrent extremity/body wall and head/neck STS;
   b. Recurrent, unresectable or stage IV retroperitoneal/intra-abdominal STS;
   c. Advanced or metastatic pleomorphic rhabdomyosarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;

5. Prescribed as subsequent therapy for all STS subtypes;
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).*

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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).*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

IV. Appendices/General Information

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

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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
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

VI. Product Availability

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

VII. References

1. Halaven Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc.; December 2021. Available at: http://www.halaven.com. Accessed June 22, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 22, 2022.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed June 22, 2022.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2022. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 22, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9179	Injection, eribulin mesylate, 0.1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: no significant changes; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added COC; references reviewed and updated.	07/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: for STS per NCCN recommendations – added "advanced" designation to extremity/body wall and head/neck STS; removed "progressive" and added "recurrent or stage IV" designation to retroperitoneal/intra-abdominal STS; added "advanced or metastatic" designation to pleomorphic rhabdomyosarcoma; added additional STS subtype options: solitary fibrous tumor and UPS; added that Halaven should be used as subsequent therapy for all STS subtypes except angiosarcoma, solitary fibrous tumor, and UPS; references reviewed and updated.	10/2020	

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2021 annual review: added combination with Margenza and clarified combination with trastuzumab is for 3rd line therapy or beyond for breast cancer per NCCN Compendium; removed off-label indication for use in undifferentiated pleomorphic sarcoma per NCCN Compendium; references reviewed and updated.	10/2021	
4Q 2022 annual review: removed coverage for angiosarcoma and solitary fibrous tumor as use is no longer supported by the NCCN Soft Tissue Sarcoma guidelines; references reviewed and updated.	10/2022	