UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1312-4 |
| Program | Prior Authorization/Notification |
| Medication | Tazverik® (tazemetostat) |
| P&T Approval Date | 3/2020, 3/3021, 3/2022, 3/2023 |
| Effective Date | 6/1/2023;<br>Oxford only: 6/1/2023 |

**1. Background:**

Tazverik (tazemetostat) is a methyltransferase inhibitor indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection, adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies or adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria[a]:**

**A. Patients less than 19 years of age**

1. **Tazverik** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. Epithelioid Sarcoma**

1. **Initial Authorization**

   a. **Tazverik** will be approved based on **all** of the following criteria:

      (1) Diagnosis of epithelioid sarcoma

**-AND-**

(2) Disease is **one** of the following

(a) Metastatic
(b) Locally advanced

**-AND-**

(3) Disease is not eligible for complete resection

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Tazverik** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Tazverik** therapy.

**Authorization will be issued for 12 months.**

**C. Follicular Lymphoma**

1. **Initial Authorization**

a. **Tazverik** will be approved based on **all** of the following criteria:

(1) Diagnosis of follicular lymphoma

**-AND-**

(2) Subsequent therapy for **one** of the following:

(a) EZH2 mutation positive relapsed/refractory disease after 2 prior therapies
(b) EZH2 wild-type or unknown relapsed/refractory disease and no satisfactory alternative treatment options

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Tazverik** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Tazverik** therapy.

**Authorization will be issued for 12 months.**

**D. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Tazverik [package insert]. Cambridge, MA: Epizyme, Inc. July 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available athttps://www.nccn.org. Accessed January 18, 2023.


| Program | Prior Authorization/Notification - Tazverik |
|---|---|
| **Change Control** | |
| 3/2020 | New program. |
| 3/2021 | Annual review. Added coverage criteria for new indication for follicular lymphoma. Updated references. |
| 3/2022 | Annual review. Added unknown EZH2 mutation status to criteria per NCCN guidelines. Updated references. |
| 3/2023 | Annual review with no changes to coverage criteria. Added state mandate footnote and updated references. |