



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1312-5
Program	Prior Authorization/Notification
Medication	Tazverik® (tazemetostat)
P&T Approval Date	3/2020, 3/3021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

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).

The National Cancer Comprehensive Network (NCCN) also recommends the use of Tazverik in classic follicular lymphoma as preferred second-line therapy irrespective of EZH2 mutation status for older or infirm patients, or third-line and subsequent therapy (if not previously given) irrespective of EZH2 mutation status in patients with indications for treatment who have relapsed/refractory disease.

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 **both** of the following criteria:

(1) Diagnosis of relapsed or refractory follicular lymphoma

-AND-

(2) **One** of the following:

(a) Subsequent therapy in EZH2 mutation positive disease after 2 prior therapies

(b) Second-line therapy irrespective of EZH2 mutation status for older or infirm patients with indications for treatment (i.e., other therapy options are not expected to be tolerable)

(c) Third-line and/or subsequent therapy (if not previously given) irrespective of EZH2 mutation status in patients with indications for treatment

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. December 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at <https://www.nccn.org>. Accessed January 23, 2024.

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.
3/2024	Annual review. Added NCCN recommendations to background section. Added criteria to relapsed/refractory follicular lymphoma based on NCCN recommendations. Updated references.