**Cigna National Formulary Coverage Policy**

**Effective Date..... 4/1/2023**
**Next Review Date..... 4/1/2024**

# Prior Authorization
# Oncology –Tazverik® (tazemetostat tablets)

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## Product Identifier(s)

64781

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## National Formulary Medical Necessity

**Cigna covers tazemetostat (Tazverik®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:**

Prior Authorization is recommended for prescription benefit coverage of Tazverik. All approvals are provided for the duration noted below.

FDA Indication(s)

1. **Epithelioid Sarcoma.** Approve for 1 year if the individual meets the following criteria (A, B, and C):
   - **A)** Individual is ≥ 16 years of age; AND
   - **B)** Individual has metastatic or locally advanced disease; AND
   - **C)** Individual is not eligible for complete resection.

2. **Follicular Lymphoma.** Approve for 1 year if the individual meets the following criteria (A, B, and C):
   - **A)** Individual is ≥ 18 years of age; AND
   - **B)** Individual has relapsed or refractory disease; AND

**C)** Individual meets ONE of the following (i or ii):
- **i.** Individual has tried at least two prior systemic therapies; OR
- **ii.** According to the prescriber, there are no appropriate alternative therapies.

## Conditions Not Covered

Tazemetostat (Tazverik®) is considered experimental, investigational or unproven for ANY other use.

## Background

**Overview**
Tazverik, an EZH2 inhibitor, is approved in the following conditions:[1]

- **Epithelioid sarcoma**, in patients ≥ 16 years of age with metastatic or locally advanced disease not eligible for complete resection.
- **Follicular lymphoma**, in the following situations:
  - Relapsed or refractory disease, in adults whose tumors are positive for an EZH2 mutation as detected by an approved test and who have received at least two prior systemic therapies.
  - Relapsed or refractory disease, in adults 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 may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

**Guidelines**
Tazverik is addressed in the following guidelines from the National Comprehensive Cancer Network:

- **Epithelioid Sarcoma:** Guidelines for soft tissue sarcoma (version 2.2022 – May 17, 2022) recommend Tazverik as a "Preferred" therapy for treatment of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.[2] No other therapies are listed for this specific subtype of soft tissue sarcoma.
- **Follicular Lymphoma:** Guidelines for B-cell lymphomas (version 2.2023 – February 8, 2023) recommend Tazverik as a third-line and subsequent therapy for follicular lymphoma, irrespective of EZH2 mutation status.[3] Tazverik is an "Other Recommended" regimen in the second-line setting for a patient who is elderly or infirm, and if none of the other therapies are expected to be tolerable in the opinion of the treating physician.

## References


1. Tazverik® tablets [prescribing information]. Cambridge, MA: Epizyme; June 2020.
2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on February 26, 2023.
3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2023 – February 8, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on February 26, 2023.


## Revision History

| Type of Revision | Summary of Changes | Approval Date |
|---|---|---|
| Annual Revision | **Follicular Lymphoma:** To align with guidelines, the requirement that the patient has an EZH2 mutation was removed from the policy. | 03/01/2023 |