PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tazverik Prior Authorization Policy
- Tazverik® (tazemetostat tablets – Epizyme)

REVIEW DATE: 03/06/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

- **Epithelioid sarcoma**, metastatic or locally advanced disease not eligible for complete resection in patients ≥ 16 years of age.
- **Follicular lymphoma**, in the following situations:
  - Relapsed or refractory disease, positive for an EZH2 mutation as detected by an approved test and in adults who have received at least two prior systemic therapies.
  - Relapsed or refractory disease, with no satisfactory alternative treatment options in adults.

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 3.2023 – December 12, 2023) recommend Tazverik as a "Preferred" therapy (category

2A) 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 1.2024 – January 18, 2024) recommend Tazverik as a third-line and subsequent therapy (category 2A) for follicular lymphoma, under "Other Recommended Regimen", irrespective of EZH2 mutation status.[3] Tazverik is a "Preferred Regimen" in the second-line setting for a patient who is elderly or infirm (irrespective of *EZH2* mutation status), and if none of the other therapies are expected to be tolerable in the opinion of the treating physician.

POLICY STATEMENT

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

- **Tazverik® (tazemetostat tablets – Epizyme)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

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

2. **Follicular Lymphoma.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or refractory disease; AND
   C) Patient meets ONE of the following (i or ii):
      i. Patient has tried at least two prior systemic therapies; OR
      ii. According to the prescriber, there are no appropriate alternative therapies.

CONDITIONS NOT COVERED

- **Tazverik® (tazemetostat tablets – Epizyme)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Tazverik® tablets [prescribing information]. Cambridge, MA: Epizyme; November 2023.

2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2023 – December 12, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on March 1, 2024.
3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2024 – January 18, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on March 1, 2024.

HISTORY

Type of Revision	Summary of Changes	Review 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
Annual Revision	No criteria change.	03/06/2024