

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Tazverik Prior Authorization Policy

- Tazverik™ (tazemetostat tablets – Epizyme)

**REVIEW DATE:** 01/29/2020; selected revision 06/24/2020

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### OVERVIEW

Tazverik, an EZH2 inhibitor, is approved in the following conditions:<sup>1</sup>

- **Epithelioid sarcoma**, in patients  $\geq 16$  years of age with a metastatic or locally advanced disease not eligible for complete resection.
- **Follicular lymphoma**, in the following situations:
  - In adults with relapsed or refractory disease, whose tumors are positive for an EZH2 mutation as detected by an approved test and who have received at least two prior systemic therapies.
  - In adults with relapsed or refractory disease 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

The National Comprehensive Cancer Network (NCCN) guidelines for soft tissue sarcoma (version 6.2019 – February 10, 2020) have been updated to recommend Tazverik for treatment of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.<sup>2</sup> No other therapies are listed for this specific subtype of soft tissue sarcoma. Generally for soft tissue sarcomas, treatment recommendations are based on anatomic site of primary disease (e.g., extremities, trunk, visceral, retroperitoneum, or head and neck).

NCCN guidelines for B-cell lymphomas (version 2.2020 – July 9, 2020) recommend Tazverik be used according to the approved indication.<sup>3</sup> This includes use of Tazverik as a subsequent therapy for follicular lymphoma, in patients with EZH2 mutation positive disease after two prior therapies, or in relapsed or refractory disease in patients who have no satisfactory alternative treatment options.<sup>3</sup>

### POLICY STATEMENT

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

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tazverik is recommended in those who meet the following criteria:

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### **FDA-Approved Indications**

- 1. Epithelioid Sarcoma.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq$  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 3 years if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has relapsed or refractory disease; AND
  - C) Patient meets ONE of the following (i or ii):
    - i. Both of the following apply (a and b):
      - a) Patient's tumor is positive for an EZH2 mutation; AND
      - b) Patient has tried at least two prior systemic therapies; OR
    - ii. According to the prescriber, there are no appropriate alternative therapies.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Tazverik is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### **REFERENCES**

1. Tazverik [prescribing information]. Cambridge, MA: Epizyme; June 2020.
  2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 6.2019 – February 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 10, 2020.
  3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2020 – July 9, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 10, 2020.
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