MEDICAL MUTUAL®

Drug Policy

Policy:	Tazverik (tazemetostat)	Annual Review Date: 02/20/2020 Last Revised Date: 07/16/2020

OVERVIEW

Tazverik, an EZH2 inhibitor, is indicated in patients ≥ 16 years of age with a metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. This indication is 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).

POLICY STATEMENT

This policy involves the use of Tazverik. Prior authorization is recommended for pharmacy benefit coverage of Tazverik. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tazverik as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tazverik be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Tazverik must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Epithelioid Sarcoma**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient has metastatic or locally advanced disease; AND
   - **B.** The patient is not eligible for complete resection; AND
   - **C.** The patient is 16 years of age or older; AND
   - **D.** The patient has an ECOG performance status of 0 to 2; AND
   - **E.** The tumors lack INI1 expression, as detected by local tests

2. **Relapsed/Refractory Follicular Lymphoma**
   Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. Tumors are positive for an EZH2 mutation, as detected by an FDA-approved test; AND
C. The patient meets one of the following:
  a. At least two prior systemic therapies for FL have been tried; OR
  b. The patient has no satisfactory alternative treatment options available

3. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

4. **Patient has been started on Tazverik**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tazverik has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tazverik [prescribing information]. Cambridge, MA: Epizyme; June 2020.
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3. Needs T, Fillman EP. Cancer, epithelioid sarcoma. Updated June 22, 2019. Available at: https://www.ncbi.nlm.nih.gov/books/NBK532911/?report=printable. Accessed on December 11, 2019.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 5.2019 – January 23, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 27, 2020.
5. Tazemetostat. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 29 January 2020. Accessed on 13 February 2020.
6. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 8 July 2020.