POLICY NUMBER UM ONC_1385	SUBJECT Tazverik™ (tazemetostat)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 02/12/20, 07/08/20	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 02/12/20, 07/08/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Tazverik (tazemetostat) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Epithelioid Sarcoma**
    a. The member has relapsed/refractory unresectable advanced or metastatic epithelioid sarcoma and Tazverik (tazemetostat) is being used as a single agent **AND**
    b. The member has contraindications, intolerance, or failure to anthracycline and/or gemcitabine- based chemotherapy.
3. **Follicular Lymphoma**

    NOTE: Tazverik (tazemetostat) is a non-preferred agent per NCH Policy & NCH Pathway.

Tazverik(tazemetostat) may be used for Follicular Lymphoma as follows:

a. The member has relapsed or refractory follicular lymphoma, and histologic transformation to a higher grade lymphoma (e.g. Diffuse Large B-cell Lymphoma) has been ruled out by biopsy **AND**

b. Tazverik (tazemetostat) will be used as a single agent when the following criteria are met:

   i. The member's lymphoma positive for EZH2 mutation as detected by an FDA-approved test (e.g. the cobas EZH2 Mutation Test) **AND** has experienced disease progression on at least 2 prior therapies

   ii. Member has no satisfactory alternative treatment options, particularly those listed in the NCH Pathway document including CVP/CHOP, Treanda (bendamustine) + Rituxan (rituximab), single agent Rituxan (rituximab), Revlimid (lenalidomide) + Rituxan (rituximab), and the patient is not a candidate for hematopoietic cell transplant (autologous or allogeneic).

III. EXCLUSION CRITERIA

1. Tazverik (tazemetostat) is being used after disease progression with the same regimen.
2. Concurrent use with other systemic therapies.
3. Dosing exceeds single dose limit of Tazverik (tazemetostat) 800 mg.
4. Treatment exceeds the maximum limit of 240 (200 mg) tablets/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Tazverik PI prescribing information. Epizyme, Inc. Cambridge, MA 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.