BlueCross BlueShield Federal Employee Program

TAZVERIK
(tazemetostat)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tazverik (tazemetostat) is an inhibitor of the methyltransferase, EZH2, and some EZH2 gain-of-function mutations including Y646X and A687V. The most well-characterized function of EZH2 is as the catalytic subunit of the polycomb repressive complex 2 (PRC2), catalyzing mono-, di-, and trimethylation of the lysine 27 of the histone H3. Trimethylation of histone H3 leads to transcriptional repression. SWItch/Sucrose Non-Fermentable (SWI/SNF) complexes can antagonize PRC2 function in the regulation of the expression of certain genes. The loss or dysfunction of certain SWI/SNF complex members can lead to aberrant EZH2 activity or expression and a resulting oncogenic dependence on EZH2 (1).

Regulatory Status

FDA -approved indications: Tazverik is a methyltransferase inhibitor indicated for the treatment of: (1)

1. Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
2. Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.
3. Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

The risk of developing secondary malignancies is increased following treatment with Tazverik. Across clinical trials of 668 adults who received Tazverik 800 mg twice daily, myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML) occurred in 0.6% of patients (1).

Tazverik can cause fetal harm when administered to pregnant women. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective non-hormonal contraception during treatment with Tazverik and for 6 months after the final dose. Males with female partners of reproductive potential should be advised to use effective non-hormonal contraception during treatment with Tazverik and for 3 months after the final dose (1).

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The safety and effectiveness of Tazverik in pediatric patients less than 16 years of age with epithelioid sarcoma have not been established. The safety and effectiveness of Tazverik in pediatric patients less than 18 years of age with follicular lymphoma have not been established (1).

Summary

Tazverik (tazemetostat) is an inhibitor of the methyltransferase, EZH2, and some EZH2 gain-of-function mutations including Y646X and A687V. The most well-characterized function of EZH2 is as the catalytic subunit of the polycomb repressive complex 2 (PRC2), catalyzing mono-, di-, and trimethylation of the lysine 27 of the histone H3. Trimethylation of histone H3 leads to transcriptional repression. SWItch/Sucrose Non-Fermentable (SWI/SNF) complexes can antagonize PRC2 function in the regulation of the expression of certain genes. The loss or dysfunction of certain SWI/SNF complex members can lead to aberrant EZH2 activity or expression and a resulting oncogenic dependence on EZH2. The safety and effectiveness of Tazverik in pediatric patients less than 16 years of age with epithelioid sarcoma have not been established. The safety and effectiveness of Tazverik in pediatric patients less than 18 years of age with follicular lymphoma have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tazverik while maintaining optimal therapeutic outcomes.

References

1. Tazverik [package insert]. Cambridge, MA: Epizyme, Inc.; August 2024.
2. NCCN Drugs & Biologics Compendium® Tazemetostat 2024. National Comprehensive Cancer Network, Inc. Accessed on October 7, 2024.