BlueCross BlueShield
Federal Employee Program

INQOVI
(decitabine and cedazuridine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Inqovi is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor. Decitabine is thought to exert its effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation and/or apoptosis. Non-proliferating cells are relatively insensitive to decitabine. Administration of cedazuridine with decitabine increases systemic exposure of decitabine (1).

Regulatory Status

FDA-approved indications: Inqovi is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups (1).

The recommended dosage of Inqovi is 1 tablet orally once daily on Days 1 through 5 of each 28-day cycle for a minimum of 4 cycles until disease progression or unacceptable toxicity. A complete or partial response may take longer than 4 cycles (1).

Myelosuppression can occur in patients treated with Inqovi. Complete blood counts should be obtained prior to initiating Inqovi and before each cycle. Then next cycle should be delayed if absolute neutrophil count (ANC) is less than 1,000/µL and platelets are less than 50,000/µL in the absence of active disease. Complete blood count should be monitored until ANC is 1,000/µL or greater and platelets are 50,000/µL or greater (1).

Inqovi can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Inqovi and for 6 months after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Inqovi and for 3 months after the last dose (1).

The safety and effectiveness of Inqovi in pediatric patients less than 18 years of age have not been

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established (1).

Summary

Inqovi is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor. Decitabine is thought to exert its effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation and/or apoptosis. Non-proliferating cells are relatively insensitive to decitabine. Administration of cedazuridine with decitabine increases systemic exposure of decitabine. The safety and effectiveness of Inqovi in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Inqovi [package insert]. Princeton, NJ: Taiho Oncology, Inc.; March 2022.
2. NCCN Drugs & Biologics Compendium® Decitabine and cedazuridine 2024. National Comprehensive Cancer Network, Inc. Accessed on October 1, 2024.