



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Daurismo (glasdegib) is an inhibitor of the Hedgehog pathway. Daurismo binds to and inhibits Smoothened, a transmembrane protein involved in hedgehog signal transduction. Daurismo in combination with low-dose cytarabine inhibits increases in tumor size and reduces the percentage of CD45+/CD33+ blasts in the marrow to a greater extent than Daurismo or low-dose cytarabine alone (1).

Regulatory Status

FDA-approved indication: Daurismo is a Hedgehog pathway inhibitor indicated, in combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy (1).

Daurismo has a boxed warning regarding embryo-fetal death or severe birth defects. Pregnancy testing should be done in females of reproductive potential prior to initiation of Daurismo treatment. Females of reproductive potential should be advised to use effective contraception during treatment with Daurismo and for at least 30 days after the last dose. Males with a pregnant partner or a female partner of reproductive potential should be advised to use condoms during treatment with Daurismo and for at least 30 days after the last dose (1).

Complete blood counts, electrolytes, renal, and hepatic function should be assessed prior to initiation of Daurismo and at least once weekly for the first month. Electrolytes and renal function should be monitored once monthly for the duration of therapy. Serum creatinine kinase levels should be obtained prior to initiating Daurismo and as indicated clinically thereafter.

Electrocardiograms (ECGs) should be monitored prior to initiation of Daurismo, approximately one week after initiation, and then once monthly for the next two months to assess for QTc prolongation (1).

The safety and effectiveness of Daurismo in pediatric patients have not been established (1).

Summary

Daurismo (glasdegib) is an inhibitor of the Hedgehog pathway. Daurismo binds to and inhibits



**BlueCross
BlueShield**

Federal Employee Program.

DAURISMO (glasdegib)

Smoothed, a transmembrane protein involved in hedgehog signal transduction. Daurismo in combination with low-dose cytarabine inhibits increases in tumor size and reduces the percentage of CD45+/CD33+ blasts in the marrow to a greater extent than Daurismo or low-dose cytarabine alone. The safety and effectiveness of Daurismo in pediatric patients have not been established (1).

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

References

1. Daurismo [package insert]. NY, NY: Pfizer Inc.; December 2024.
2. NCCN Drugs & Biologics Compendium® Glasdegib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.