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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 7, 2018
Subject:	Daurismo	**Page:**	1 of 4

Last Review Date: December 8, 2023

Daurismo

Description

Daurismo (glasdegib)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Daurismo may be considered **medically necessary** if the conditions indicated below are met.

Daurismo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Newly-diagnosed acute myeloid leukemia (AML)

AND ALL of the following:

1. Used in combination with low-dose cytarabine
2. Patient is 75 years of age or older **OR** patient has comorbidities that preclude the use of intensive induction chemotherapy
3. Prescriber agrees to monitor electrocardiograms (ECGs) for QTc prolongation
4. Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 30 days after the last dose
5. Prescriber agrees to advise males with female partners of reproductive potential to use condoms during treatment and for at least 30 days after the

last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Acute myeloid leukemia (AML)

AND ALL of the following:

1. Used in combination with low-dose cytarabine
2. **NO** disease progression or unacceptable toxicity
3. Prescriber agrees to monitor electrocardiograms (ECGs) for QTc prolongation
4. Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 30 days after the last dose
5. Prescriber agrees to advise males with female partners of reproductive potential to use condoms during treatment and for at least 30 days after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity Limit
25 mg tablets	180 tablets per 90 days **OR**
100 mg tablets	90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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. 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.; March 2023.
2. NCCN Drugs & Biologics Compendium® Glasdegib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2023.

Policy History

Date	Action
December 2018	Addition to PA
March 2019	Annual review
June 2020	Annual editorial review and reference update
March 2021	Annual editorial review
March 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.