

Clinical Pharmacy Program Guidelines for Daurismo

Program	Prior Authorization
Medication	Daurismo™ (glasdegib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	1/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Daurismo™ (glasdegib) 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

The National Cancer Comprehensive Network (NCCN) also recommends the use of Daurismo for relapsed/refractory disease as a component of repeating the initial successful induction regimen if late relapse (≥ 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance.

2. Coverage Criteria:

<p>A. <u>Acute Myeloid Leukemia</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Daurismo will be approved based on <u>all</u> of the following criteria:</p> <p>(1) One of the following:</p> <p>(a) Diagnosis of newly-diagnosed acute myeloid leukemia (AML)</p> <p>(b) Relapsed/refractory disease with all of the following:</p> <p>i. Given as a component of repeating the initial successful induction regimen</p> <p>ii. Late relapse (≥ 12 months since induction regimen)</p> <p>iii. Initial therapy was not administered continuously</p>

iv. Initial therapy was not stopped due to development of clinical resistance

-AND-

(2) Daurismo therapy to be given in combination with low-dose cytarabine

-AND-

(3) **One** of the following:

- (a) Patient is ≥ 75 years old
- (b) Patient has significant comorbidities that preclude the use of intensive induction chemotherapy (e.g., severe cardiac disease, ECOG performance status ≥ 2 , baseline creatinine >1.3 mg/dL)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Daurismo** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Daurismo therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Daurismo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Daurismo** will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Daurismo therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Daurismo [package insert]. Pfizer Labs: New York, NY; March 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 18, 2020.

Program	Prior Authorization
Change Control	
Date	Change
1/2019	New program
1/2020	Added examples of significant comorbidities. Updated references.
1/2021	Annual review. Updated criteria per NCCN recommendations. Updated references.