UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1270-7
Program	Prior Authorization/Notification
Medication	Daurismo™ (glasdegib)
P&T Approval Date	1/2019, 1/2020, 1/2021, 1/2022, 1/2023, 1/2024, 1/2025
Effective Date	4/1/2025

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.

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.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Acute Myeloid Leukemia</u>

1. **<u>Initial Authorization</u>**

   a. **Daurismo** will be approved based on **<u>all</u>** of the following criteria:

      (1) **<u>One</u>** of the following:

         (a) Diagnosis of newly-diagnosed acute myeloid leukemia (AML)
         (b) Relapsed/refractory disease with **all** of the following:

i. Given as a component of repeating the initial successful induction regimen
ii. Late relapse (≥12 months since induction regimen)
iii. Initial therapy was not administered continuously
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.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 22, 2024.

Program	Prior Authorization/Notification - Daurismo™ (glasdegib)
Change Control	
1/2019	New program
1/2020	Annual review. Added general NCCN recommendations for use criteria. Updated coverage criteria to include examples of significant comorbidities and references.
1/2021	Annual review. Updated criteria per NCCN recommendations. Updated references.
1/2022	Annual review with no change to clinical criteria. Updated reference.
1/2023	Annual review with no change to clinical criteria. Added state mandate and updated references.
1/2024	Annual review with no change to clinical criteria. Updated reference.
1/2025	Annual review with no change to clinical criteria. Updated references.