Clinical Policy: Glasdegib (Daurismo)

Reference Number: ERX.SPA.317
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Glasdegib (Daurismo™) is a Hedgehog (Hh) pathway inhibitor

FDA Approved Indication(s)
Daurismo is 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Daurismo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (must meet all)**:**

1. Diagnosis of AML;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For Daurismo requests, member must use glasdegib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets one of the following (a, b, or c):
   a. Age ≥ 75 years;
   b. Medical justification supports inability to use intensive induction chemotherapy (*see Appendix D for examples*);
   c. Member responded to then relapsed after Daurismo induction therapy ≥ 12 months ago;
6. Prescribed in combination with low-dose cytarabine;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 100 mg (1 tablet) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acute Myeloid Leukemia (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Daurismo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Daurismo requests, member must use glasdegib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. Prescribed in combination with low-dose cytarabine;
5. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 100 mg (1 tablet) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AML: acute myeloid leukemia
FDA: Food and Drug Administration
Hh: Hedgehog

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

Appendix D: General Information

- The management of AML is divided into induction and postremission (consolidation) therapy. Induction usually includes intensive chemotherapy (e.g., standard [100-200 mg/m^2] or high [2 g/m^2] dose cytarabine, fludarabine), but many adults with AML are unable to undergo intensive chemotherapy due to its toxicities. Some examples of reasons why members may not qualify for intensive induction chemotherapy include, but are not limited to:
  - Baseline Eastern Cooperative Oncology Group (ECOG) performance status ≥ 2
  - Severe cardiac comorbidity (e.g., history of congestive heart failure requiring treatment, ejection fraction ≤ 50%, or chronic stable angina)
  - Baseline creatinine > 1.3 mg/dL
  - Member is age ≥ 60 years and declines intensive chemotherapy

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AML	100 mg PO QD on days 1 to 28 in combination with cytarabine 20 mg SC BID on days 1 to 10 of each 28-day cycle	100 mg/day

VI. Product Availability

Tablets: 25 mg, 100 mg

VII. References

1. Daurismo Prescribing Information. New York, NY: Pfizer, Inc.; March 2020. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=11336. Accessed November 9, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 9, 2021.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed November 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.08.19	02.19
1Q 2020 annual review: AML - NCCN recommended use added for relapsed disease; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	11.19.19	02.20
RT4: Removed limitations of use from FDA approved indications section per labeling update	03.24.20	
1Q 2021 annual review: oral oncology generic redirection language added; references reviewed and updated.	10.12.20	02.21
1Q 2022 annual review: no significant changes; clarified oral oncology generic redirection language to “must use”; references reviewed and updated.	11.09.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.