Clinical Policy: Glasdegib (Daurismo)

Reference Number: PA.CPPHAR.413
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

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.

Limitation(s) of use: Daurismo has not been studied in patients with the comorbidities of severe renal impairment or moderate-to-severe hepatic impairment.

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.

It is the policy of health plans affiliated with PA Health & Wellness® 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. Member meets one of the following (a or b):
   a. Age ≥ 75 years;
   b. Medical justification supports inability to use intensive induction chemotherapy (*see Appendix D for examples*);
5. Prescribed in combination with low-dose cytarabine;
6. 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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Acute Myeloid Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
1. Member is responding positively to therapy;
2. Prescribed in combination with low-dose cytarabine;
3. 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*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CPPMN.53 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): Daurismo is embryotoxic, fetotoxic, and teratogenic in animals. Since Daurismo can cause embryo-fetal death or severe birth defects when administered to a pregnant woman, conduct pregnancy testing in females of productive potential prior to initiation of Daurismo. Advise males and females to use effective contraception.

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.; November 2018. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=11336. Accessed December 14, 2018.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed December 14, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	