

Reference number(s)
2793-A

SPECIALTY GUIDELINE MANAGEMENT

DAURISMO (glasdegib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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 of Use: Daurismo has not been studied in patients with the comorbidities of severe renal impairment or moderate-to-severe hepatic impairment.

Compendial Uses

1. Post remission therapy following response to previous therapy with the same regimen
2. Relapsed/refractory disease as a component of repeating the initial successful induction regimen

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted for treatment of AML when all of the following criteria is met (A, B, and C):

- A. The requested medication is used in combination with cytarabine
- B. One of the following criteria is met:
 1. Member is 75 years of age or older.
 2. Member has comorbidities that preclude treatment with intensive induction chemotherapy.
- C. The requested medication will be used as treatment for induction therapy, post-remission therapy, or relapsed/refractory disease.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Daurismo [package insert]. New York, NY: Pfizer, Inc.; November 2018.

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2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc.
Available at: <https://www.nccn.org> Accessed June 18, 2019.