PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Daurismo Prior Authorization Policy
- Daurismo™ (glasdegib tablets – Pfizer)

REVIEW DATE: 12/02/2020

OVERVIEW

Daurismo, a hedgehog pathway inhibitor, is indicated, in combination with low-dose cytarabine, for the treatment of newly-diagnosed **acute myeloid leukemia** (AML) in adults who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.[1]

Disease Overview

AML is a heterogeneous hematologic malignancy that is hallmarked by clonal expansion of myeloid blasts in the peripheral blood, bone marrow, and/or other tissues.[2] It is a rather common form of acute leukemia in adults and it has the largest number of annual deaths from leukemias in the US. Around 19,940 people will be diagnosed with AML in 2020, and 11,180 patients will die from the condition. The median age at diagnosis is 66 years of age. Over one-half and approximately one-third of patients receive the diagnosis at ≥ 65 and ≥ 75 years of age, respectively. The incidence of AML, along with myelodysplastic syndrome (MDS) is rising as patients become older. Environmental factors play a role and include prolonged exposure to petrochemicals; solvents such as benzene; pesticides; and ionizing radiation. Also, two cytotoxic agents that are associated with therapy-related MDS/AML are alkylating agents (e.g., cyclophosphamide) and topoisomerase inhibitors (e.g., doxorubicin). Antimetabolite therapy, notably fludarabine, has also been associated with MDS/AML in patients with lymphoproliferative disorders, especially when given in combination with alkylating agents. Molecular or karyotypic abnormalities can also be identified. Treatment of AML can involve the following modalities at various stages: chemotherapy, radiation therapy, chemotherapy with stem cell transplant, and other drug therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines address Daurismo.[2]

- **Acute Myeloid Leukemia:** NCCN guidelines for AML (version 2.2021 – November 12, 2020) recommended Daurismo with low-dose cytarabine for patients ≥ 60 years of age who are not candidates for intensive remission induction therapy or declines without an actionable mutation (category 2A). Daurismo is also recommended with low-dose cytarabine as post-induction therapy for patients ≥ 60 years of age who had a response to previous low-intensity therapy. (category 2A).

Safety

Daurismo has a Boxed Warning regarding embryofetal toxicity.[1] Also, patients receiving Daurismo may develop QTc prolongation and ventricular arrhythmias. Serious adverse reactions were reported in 79% of patients given Daurismo plus low-dose cytarabine and the most common were febrile neutropenia (29%), pneumonia (23%), hemorrhage (12%), anemia (7%), and sepsis (7%). Consider specific drug-drug interactions among patients given Daurismo (e.g., strong cytochrome P450 [CYP]3A4 inhibitors, strong CYP3A4 inducers, QTc prolonging medications).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Daurismo. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Daurismo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia (AML).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is using the medication in combination with cytarabine; AND
   - **B)** Patient must meet one of the following criteria (i or ii):
     - **i.** Patient is using the medication for treatment induction and meets one of the following (a or b):
       - **a)** Patient is ≥ 75 years of age; OR
       - **b)** Patient meets both of the following [(1) and (2)]:
         - **(1)** Patient is ≥ 18 years of age; AND
         - **(2)** According to the prescriber, the patient has comorbidities that precludes the use of intensive induction chemotherapy; OR
     - **ii.** Patient meets both of the following (a and b):
       - **a)** Patient is ≥ 18 years of age; AND
       - **b)** Patient is continuing the medication as post-induction therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Daurismo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Daurismo™ tablets [prescribing information]. New York, NY: Pfizer; November 2018.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 2.2021 – November 12, 2020). © 2010 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 4, 2020.