BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 2/21/2019
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

DAURISMO™ (glasdegig) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Daurismo (glasdegib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. A confirmed diagnosis of **ONE** of the following:
     a. Used in combination with low-dose cytarabine for treatment of newly-diagnosed Acute Myeloid Leukemia (AML) in patients who are ≥75 years of age, or who have significant comorbid conditions (i.e., severe cardiac disease, Eastern Co-operative Oncology Group (ECGO) performance status ≥ 2, or baseline creatinine > 1.3 mg/dL) that preclude use of intensive induction chemotherapy

     b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  3. Individual does not have severe renal impairment (CrCl < 30 mL/min)

  4. Individual does not have moderate (total bilirubin 1.5–3 × ULN and any AST) to severe (total bilirubin > 3 × ULN and any AST) hepatic impairment

  5. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Negative pregnancy test in a woman of child bearing potential
     b. Complete blood count
     c. Comprehensive metabolic panel for electrolytes, renal function, hepatic function
     d. Serum creatine kinase
     e. Electrocardiogram

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Daurismo (glasdegib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has not worsened while on therapy

  3. Individual has been adherent with the medication

  4. Individual does not have severe renal impairment (CrCl < 30 mL/min)

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5. Individual does not have moderate (total bilirubin 1.5–3 × ULN and any AST) to severe (total bilirubin > 3 × ULN and any AST) hepatic impairment

6. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. QTc interval prolongation with life-threatening arrhythmia
        ii. Platelets < 10,000 cells/mm^3 for more than 42 days in the absence of disease
        iii. Neutrophil count < 500 cells/mm^3 for more than 42 days in the absence of disease
        iv. Any grade 4 non-hematologic toxicity

7. There are no significant interacting drugs

Renewal duration: 12 months

Description:

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

AML is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. Approximately half of the adults diagnosed with AML are not treated with intensive chemotherapy because of comorbidities and chemotherapy related toxicities

Definitions:

Eastern Co-operative Oncology Group (ECGO) Performance Status:

Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physical strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities, up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled, cannot carry on any self-care, totally confined to bed or chair
5	Dead
Oken, MM, Creech, RH, Tormey, DC, et al.: Toxicity and Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

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Resources:

Daurismo (glasdegib) product information, revised by Pfizer Laboratories Div Pfizer Inc. 03-2020, at DailyMed http://dailymed.nlm.nih.gov. Accessed January 30, 2021.

Daurismo (glasdegib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: http://www.nccn.org. Accessed January 30, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.