Daurismo™ (glasdegib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Daurismo 25 mg tablets: 3 tablets per day
- Daurismo 100 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 100 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**
- Patient has a baseline QTc interval of ≤ 470 ms AND patient does not have a history of long QT syndrome; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to initiating therapy *(females of reproductive potential and males should use effective contraception during and for at least 30 days after treatment)*; **AND**

Universal Criteria [1]

- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Baseline creatine phosphokinase (CPK) level will be obtained prior to initiating therapy and will be measured as clinically indicated while on treatment; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

- Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**
- Coadministration with moderate CYP3A4 inducers (e.g., efavirenz, bosentan, phenobarbital, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with QTc prolonging drugs (e.g., ciprofloxacin, amitriptyline, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Acute Myeloid Leukemia † ‡ Φ [1,2,4]

- Used for newly diagnosed disease; **AND**
  - Patient is ≥ 75 years of age OR patient has significant comorbid conditions (e.g., severe cardiac disease, EGOG performance status score of ≥ 2, serum creatinine > 1.3 mg/dL, etc.); **AND**
    - Used in combination with low-dose cytarabine; **AND**
      - Used for treatment induction in patients without actionable mutations who are not candidates for intensive induction therapy; **OR**
      - Used as follow-up therapy after induction therapy following a response to previous lower intensity therapy with the same regimen; **OR**
      - Used as consolidation therapy as a continuation of a low-intensity regimen used for induction in patients with poor-risk AML with and without TP53-mutation or del17p abnormality, therapy-related AML other than CBF-AML, antecedent MDS/CMML, or cytogenetic changes consistent with MDS (AML-MRC); **OR**
- Used for relapsed or refractory disease; **AND**
  - Used as a component of repeating the initial successful induction regimen if it has been ≥12 months since receiving the induction regimen; **AND**
  - Treatment was not administered continuously and not stopped due to development of clinical resistance

† FDA Approved Indication(s) ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic

response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: QTc-interval prolongation (i.e., interval ≥ 500 ms and/or interval prolongation with signs and symptoms of severe arrhythmia), musculoskeletal adverse reactions (which may include CPK elevations), etc.

V. Dosage/Administration

Indication	Dose
AML	Administer 100 mg orally once daily on days 1 to 28 in combination with cytarabine 20 mg administered subcutaneously twice daily on days 1 to 10 of each 28-day cycle in the absence of unacceptable toxicity or loss of disease control. For patients without unacceptable toxicity, treat for a minimum of 6 cycles to allow time for clinical response.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals

NDC:

- Daurismo 100 mg tablets: 00069-1531-xx
- Daurismo 25 mg tablets: 00069-0298-xx

VII. References

1. Daurismo [package insert]. New York, NY; Pfizer Labs.; March 2023. Accessed June 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) glasdegib. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2023.
3. Cortes JE, Heidel FH, Heuser M, et al. A Phase 2 Randomized Study of Low Dose Ara-C with or without Glasdegib (PF-04449913) in Untreated Patients with Acute Myeloid Leukemia or High-Risk Myelodysplastic Syndrome. Blood 2016 128:99.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia 3.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer

Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C92.00	Acute myeloblastic leukemia not having achieved remission
C92.01	Acute myeloblastic leukemia in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.51	Acute myelomonocytic leukemia in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC