Daurismo™ (glasdegib)
(Oral)

Document Number: IC-0419

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Dates Reviewed: 01/2019, 07/2019, 07/2020

I. Length of Authorization

Coverage will be provided for six 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]

- Patient is 18 years or older; **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

- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, 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., bosentan, modafinil, 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 [1,2,3]

- Patient does not have a t(9:22) cytogenetic translocation or acute promyelocytic leukemia; **AND**
  - Patient is 75 years or older OR patient is unable to receive intensive induction chemotherapy due to significant comorbidities (e.g., severe cardiac disease *[i.e., LVEF < 50% or a cumulative anthracycline dose equivalent to 400-550 mg/m² of daunorubicin or 150 mg/m² of idarubicin, etc.]*, performance status score of ≥ 2, serum creatinine > 1.3 mg/dL, etc.); **AND**
    - Used in combination with low-dose cytarabine; **AND**
    - Patient has newly diagnosed acute myeloid leukemia; **AND**
      - Used for treatment induction when not a candidate for or decline intensive therapy; **OR**
      - Used as post-induction therapy following a response to previous lower intensity therapy with the same regimen; **OR**
- Used for relapsed, refractory disease; **AND**
  - Used as re-induction therapy as a component of the initial successful induction regimen if the relapse occurred ≥ 12 months since induction

† FDA approved indication(s) ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria

Authorizations 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), etc.

V. Dosage/Administration

Indication	Dose

AML	100 mg orally once daily on days 1 to 28 in combination with cytarabine 20 mg 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 2020. Accessed June 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) glasdegib. National Comprehensive Cancer Network, 2020. 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 2020.
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 3.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.

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

ICD-10	ICD-10 Description
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
C94.00	Acute erythroid leukemia not having achieved remission
C94.01	Acute erythroid leukemia in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia in remission
C94.22	Acute megakaryoblastic 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: http://www.cms.gov/medicare-coverage-database/search/advanced-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.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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