glasdegib (Daurismo™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO033

Description

Glasdegib (Daurismo) is an orally administered hedgehog pathway inhibitor.

Length of Authorization

- Initial: six months
- Renewal: 12 months

Quantity limits

glasdegib (Daurismo)	Indication	Quantity Limit	*DDID*
25 mg tablets	Acute myeloid leukemia	60 tablets/30 days	204939
100 mg tablets	Acute myeloid leukemia	30 tablets/30 days	204938

Initial Evaluation

I. Glasdegib (Daurismo) may be considered medically necessary when the following criteria are met:
   A. Prescribed by an oncologist or hematologist; **AND**
   B. A diagnosis of newly-diagnosed acute myeloid leukemia (AML) when the following are met:
      1. Age 75 years and older **OR**
      2. Have comorbidities that preclude use of intensive induction chemotherapy such as:
         i. Baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2
         ii. Severe cardiac comorbidity (i.e. LEVF <45%)
         iii. Baseline Scr >1.3 (CrCl ≥30 to <45 mL/min)
         AND
      3. Does not have hepatic or severe renal impairment (CrCl <30 mL/min); **AND**
      4. Used in combination with low-dose cytarabine (LDAC)

II. Glasdegib (Daurismo) is considered investigational when used for all other conditions, including but not limited to:
   A. Acute Myeloid Leukemia – Previously treated
   B. Monotherapy use or used in combination with azacitidine or decitabine

Renewal Evaluation

I. Clinical documentation of response to treatment, such as stabilization or improvement of disease; **AND**
II. Absence of unacceptable toxicity from the medication

Supporting Evidence

I. Glasdegib (Daurismo) is FDA-approved, in combination with LDAC, for the treatment of newly-diagnosed AML in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
II. Patients included in the trial were 55 years and older and met one of the following: at least 75 years old, severe cardiac disease, baseline Eastern Cooperative Oncology Group performance stats (ECOG PS) of 2, or a baseline serum creatinine > 1.3 mg/dL. The study did not include patients with an ECOG PS of 3, severe renal, or hepatic impairment, all of which are comorbidities that would preclude use of intensive chemotherapy.
III. Pivotal trial leading to glasdegib (Daurismo) approval met the primary efficacy outcome of overall survival, with median OS of 8.3 months in the combination arm versus 4.3 months with LDAC alone.

Investigational or Not Medically Necessary Uses

I. Acute Myeloid Leukemia – Previously treated
    A. Pivotal trials leading to FDA approval were specifically in the previously untreated setting. Use in the relapsed/refractory setting is not supported by clinical trials nor cited within NCCN AML guidelines.
II. Monotherapy use or used in combination with azacitidine or decitabine
    A. Monotherapy use or use in combination with azacitidine or decitabine is not supported within guidelines or clinical evidence. Trials are currently underway evaluating the use in combination with azacitidine or decitabine, data has not yet been published.

References

1. Cortes JE, Heidel FH, Hellmann A, et al. Randomized comparison of low dose cytarabine with or without glasdegib in patients with newly diagnosed acute myeloid leukemia or high-risk myelodysplastic syndrome. Leukemia. 2018
2. Daurismo [prescribing information]. Pfizer Labs, Inc.: New York, NY. November 2018.
3. Venclexta [prescribing information]. Genentech: San Francisco, CA. November 2018.
4. U.S. Food and Drug Administration. FDA approves new treatment for patients with acute myeloid leukemia. Published November 21, 2018. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626443.htm

5. NCCN Clinical Practice Guideline in Oncology: Acute Myeloid Leukemia. Version 3.2018. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Updated November 30, 2018.
6. Cortes, J. E., Heidel, F. H., 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, 128(22), 99. Accessed December 03, 2018.
7. Martinelli, G., Oehler, V. G., Papayannidis, C., et al. Treatment with PF-04449913, an oral smoothened antagonist, in patients with myeloid malignancies: a phase 1 safety and pharmacokinetics study. The Lancet Hematology, 2(8), e339-e346.
8. Erba, Harry P. "Finding the optimal combination therapy for the treatment of newly diagnosed AML in older patients unfit for intensive therapy." Leukemia research 39.2 (2015): 183-191.

Policy Implementation/Update:

Date Created	January 2019
Date Effective	February 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date