COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 11, 2023

OFF-LABEL ID #: 2519

DRUG NAME: Gilteritinib

OFF-LABEL USE: Acute myeloid leukemia, disease; Newly diagnosed, with FLT3 mutation, in patients ineligible for intensive chemotherapy

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C, L, R, S *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Wang, ES, Montesinos, P, Minden, MD, et al: Phase 3 trial of gilteritinib plus azacitidine vs azacitidine for newly diagnosed FLT3mut+ AML ineligible for intensive chemotherapy. Blood Oct 27, 2022; Vol 140, Issue 17; pp. 1845-1857.	S
None Listed: Gilteritinib plus azacitidine combination shows promise in newly diagnosed FLT3-mutated AML. Oncologist Feb 2021; Vol 26, Issue Suppl 1; p. S10.	4

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Megan Smith	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Todd Gersten	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
IBM MICROMEDEX	Ineffective	Class III: Not Recommended		B

Todd Gersten	Ineffective	Class III: Not Recommended	Gilteritinib failed to improve survival and led to more toxicity when added to azacitidine in the management of newly diagnosed FLT3 mutated AML (in patients ineligible for intensive chemotherapy) when evaluated in a small randomized study.	
Richard LoCicero	Ineffective	Class III: Not Recommended	In a single phase III, open-label trial, the addition of gilteritinib to azacitidine did not improve overall survival in the study population.	
Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of Gilteritinib with azacitidine showed no additional benefit when compared to azacitidine monotherapy in this small study. Patients treated were newly diagnosed AML patients. The adverse effect profile with the combination treatment was more pronounced than the single agent therapy.	