CADTH

pan-Canadian Oncology Drug Review Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation (Sponsor)

Gemtuzumab Ozogamicin (Mylotarg) for Acute Myeloid Leukemia

April 2, 2020

Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Mylotarg (gemtuzumab Ozogamicin) - In combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of adult patients with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia
Eligible Stakeholder Role in Review (Sponsor and/or Manufacturer, Patient Group, Clinical Group):	Manufacturer
Organization Providing Feedback	Pfizer Canada ULC

**The pCODR program may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by the pCODR program.*

3.1 Comments on the Initial Recommendation

a) Please indicate if the eligible stakeholder agrees, agrees in part, or disagrees with the Initial Recommendation:

☒ agrees ☐ agrees in part ☐ disagree

No comments

b) Please indicate if the eligible stakeholder agrees, agrees in part, or disagrees with the provisional algorithm:

☒ agrees ☐ agrees in part ☐ disagree

No comments

c) Please provide editorial feedback on the Initial Recommendation to aid in clarity. Is the Initial Recommendation or are the components of the recommendation (e.g., clinical and economic evidence or provisional algorithm) clearly worded? Is the intent clear? Are the reasons clear?

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
p.2	Potential next steps for stakeholders	Paragraph 1: pERC agreed that cytogenic testing status is required to determine status prior to initiating treatment with gemtuzumab ozogamicin. The Committee noted that cytogenetics testing is available in all jurisdictions; however, it was also noted that there are variations in the turnaround timing of the results. As a result, pERC noted that it would be ideal for jurisdictions to require timely cytogenetic testing and should a patient's unknown cytogenetic status become known as adverse, it recommends gemtuzumab ozogamicin be discontinued. pERC does not recommend the use of gemtuzumab ozogamicin for patients with adverse cytogenetics.	It is unclear based on the highlighted sentences, what the definition of unknown cytogenetic status is. According to the pERC recommendation (p.5, second paragraph: patients are eligible to start induction therapy with gemtuzumab ozogamicin when either the cytogenetic test confirms that the cytogenetic status is favourable, intermediate, or unknown (that is, because the test was unsuccessful) or when their cytogenetic test results are not yet available. Suggested changes: pERC agreed that cytogenetic testing status is required to determine status prior to initiating treatment with gemtuzumab ozogamicin. The Committee noted that cytogenetics testing is available in all jurisdictions; however, it was also noted that there are variations in the turnaround timing of the results. As a result, pERC noted that it would be ideal for jurisdictions to require timely cytogenetic testing. In the event where their cytogenetic status is unknown (that is, because the test was unsuccessful) or when their cytogenetic test results are not yet available, gemtuzumab ozogamicin could be initiated at induction therapy. Patients are eligible to start consolidation therapy with gemtuzumab ozogamicin when their cytogenetic tests confirm that the cytogenetic status is favourable, intermediate, or unknown (because the test was unsuccessful). pERC recommends that should a patient's unknown cytogenetic status become known as adverse, gemtuzumab ozogamicin should be discontinued.
p.14	Companion Diagnostic Test	pERC agreed that cytogenetic testing status is required prior to initiating treatment with gemtuzumab ozogamicin. The Committee noted that cytogenetics testing is available in all jurisdictions; however, it was also noted that variation in the	It is unclear based on the highlighted sentence, what the definition of unknown cytogenetic status is. According to the pERC recommendation (p.5, second paragraph: patients are eligible to start induction therapy with gemtuzumab ozogamicin when either the cytogenetic test confirms that the cytogenetic status is favourable, intermediate, or unknown (that is, because the test was unsuccessful) or when their cytogenetic test results are not yet available. pERC agreed that cytogenic testing status is required to determine status prior to initiating treatment with gemtuzumab ozogamicin. The Committee noted that

		timing of the results of the testing exists. As a result, pERC noted that it would be ideal for jurisdictions to have cytogenetic testing done in a timely fashion.	cytogenetics testing is available in all jurisdictions; however, it was also noted that there are variations in the turnaround timing of the results. As a result, pERC noted that it would be ideal for jurisdictions to require timely cytogenetic testing. In the event where their cytogenetic status is unknown (that is, because the test was unsuccessful) or when their cytogenetic test results are not yet available, gemtuzumab ozogamicin could be initiated at induction therapy. Patients are eligible to start consolidation therapy with gemtuzumab ozogamicin when their cytogenetic tests confirm that the cytogenetic status is favourable, intermediate, or unknown (because the test was unsuccessful). pERC recommends that should a patient's unknown cytogenetic status become known as adverse, gemtuzumab ozogamicin should be discontinued.

3.2 Comments Related to Eligible Stakeholder Provided Information

Notwithstanding the feedback provided in part a) above, please indicate if the Stakeholder would support this Initial Recommendation proceeding to Final pERC Recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

☒	Support conversion to Final Recommendation. Recommendation does not require reconsideration by pERC.	☐	Do not support conversion to Final Recommendation. Recommendation should be reconsidered by pERC.

If the eligible stakeholder does not support conversion to a Final Recommendation, please provide feedback on any issues not adequately addressed in the Initial Recommendation based on any information provided by the Stakeholder in the submission or as additional information during the review.

Please note that new evidence will be not considered at this part of the review process, however, it may be eligible for a Resubmission. If you are unclear as to whether the information you are providing is eligible for a Resubmission, please contact the pCODR program.

Additionally, if the eligible stakeholder supports early conversion to a Final Recommendation; however, the stakeholder has included substantive comments that requires further interpretation of the evidence, including the provisional algorithm, the criteria for early conversion will be deemed to have not been met and the Initial Recommendation will be returned to pERC for further deliberation and reconsideration at the next possible pERC meeting.