CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

venetoclax (Venclexta)

AbbVie Corporation

Indication: In combination with azacitidine or low-dose cytarabine is indicated for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

July 22, 2021

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0239-000
Brand name (generic)	venetoclax
Indication(s)	In combination with low dose cytarabine for the treatment of patients with newly diagnosed AML who are 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy
Organization	Canadian Leukemia Study Group (CLSG)
Contact information[a]	Name: Andre C. Schuh Email: [redacted] Phone: [redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☐
	No	☒

We are writing again on behalf of cross-country Canadian acute leukemia treating physicians, in response to the 'Do Not Reimburse' recommendation made by CADTH regarding *Venetoclax in combination with low dose cytarabine (LDAC) for the treatment of patients with newly diagnosed AML who are 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy*. CLSG welcomes the opportunity to respond.

The use of LDAC in older or infirm patients ineligible for intensive chemotherapy (IC) for reasons of either geography or social circumstances, and are not able to attend clinic regularly, has provided a useful option for these patients, although with low efficacy. A LDAC-based regimen is also optimal for patients with secondary AML arising from a prior MDS treated with a hypomethylating agent (HMA). A combination treatment that increases the efficacy of LDAC without increasing toxicity, therefore represents a major unmet medical need for Canadian patients. We believe that the combination of venetoclax with LDAC (as compared to placebo/LDAC in the randomized double-blind placebo controlled VIALE-C trial) meets this need. When the totality of available evidence is considered, it is clear that in patients with AML, the Venetoclax plus LDAC combination is superior to LDAC alone.

We are thus dismayed by the CADTH 'Do Not Reimburse' recommendation, which we believe, will hinder acute leukemia care in Canada. Our views regarding the venetoclax/LDAC combination were already articulated clearly in our original stakeholder feedback document, which seemingly was not found to be compelling. So we won't just repeat the same argument now. However, there are a number issues that we would like to address nonetheless:

1. Viale-C Study Outcomes

Not surprisingly, the fact that the Viale-C study failed to meet its primary endpoint features prominently in the CADTH recommendation. While we cannot argue with this fact, we would like to point out that the study outcome likely relates more to study design issues (particularly when VIALE-C design is compared to that of VIALE-A) than to the failure of the Venetoclax/LDAC combination. This notion has been discussed widely (for example, see *Wei, AH et al. Harnessing the Therapeutic Value of Venetoclax: A Breakthrough Therapy in Acute Myeloid Leukemia. JCO 2021 [available online June 4, 2021]*).

In addition to these widely publicized trial issues, we have additional specific comments:

1.i. Health Canada review.
The decision to not reimburse was based upon the trial failing to meet its primary outcome by not demonstrating a statistically significant difference in overall survival in the pre-planned analysis cut-off date of 12 months as noted in page 5 of the Review in the paragraph Efficacy Results, under the heading of Clinical Evidence. However, it is also noted later in the same paragraph that Health Canada still granted venetoclax plus low dose cytarabine a notice of compliance "because of the totality of the evidence" with several analyses of other data provided for the trial as summarized further in Efficacy Results on page 6. We believe that putting all these results in context portrays a more complete picture of the unmet clinical need that has been successfully addressed by the trial results.

1.ii. Preplanned analysis at 12 months.
Many patients in the venetoclax and LDAC arm were censored at the time of this initial analysis, and therefore the median overall survival was an estimate. By contrast, in the 18 month analysis (after 6 months of further follow-up) the median survival had been reached in both groups, and the difference in OS was statistically significant (8.4 months in the venetoclax/LDAC group vs 4.1 months in the placebo/LDAC group. Furthermore, a multi-variable COX regression analysis of the preplanned analysis at 12 months did show a significant effect of the treatment arms (HR of 0.67 with confidence interval between 0.47 and 0.96, with a P value of 0.03).

1.iii. Timing of pre-planned analyses.
As listed helpfully on page 6 of the review, several other extremely important clinical analyses at the preplanned analysis time were statistically significant between study arms. Notably, the CR/CRi rates were markedly different between the two arms: 48% in the venetoclax plus LDAC group, versus 13% in the LDAC alone group. Furthermore, what is also extremely relevant clinically is that the majority of these complete remissions were obtained within one cycle, and therefore early assessment of treatment futility allowed earlier further decision-making and counselling.

1.iv. Duration of remission.
The duration of remission in those patients who attained CR at time of the preplanned analysis was also statistically and clinically significantly between the two arms: 10.8 vs 6.2 months. As the percent of patients obtaining remission, and the duration of a complete remission, are known strong determinants of overall survival for all forms of leukemia treatment, these two positive results at the time of the pre-planned analysis suggest very strongly that the difference seen for OS as assessed by HR at this time interval, even though not yet statistically "significant" (p=0.11), was real.

1.v. Transfusion independence.
At the time of the primary analysis, as a consequence of the achievement of complete remission, the transfusion independence rate in the venetoclax/LDAC arm (37.1%) was more than double that of the placebo/LDAC arm (16.2%). The achievement of transfusion independence is widely recognized to be a highly significant clinical outcome in older patients with AML receiving non-intensive treatment.

Specifically, it is the universal experience of leukemia treating physicians, including all members of the CLSG Board, that the need for ongoing transfusions in a frail AML population is a significant detriment to quality of life, not only for physiologic reasons of insufficient oxygen delivery, but also for major social and financial reasons - avoiding the need for frequent clinic visits with often lengthy bi-directional travel times and long clinic waits, parking costs, and the need for other family members to attend etc.

The major importance of this outcome with respect to patient (and caregiver) quality of life and well-being, even independently of an effect on survival, cannot be overstated.

1.vi. Toxicity.
It is notable that the important benefits that resulted from the Venetoclax/LDAC combination vs. LDAC alone, were obtained without any significant increase in toxicity, as is summarized nicely in the Harms Result analysis on page 7. While there are differences in neutropenia rates (45.8% vs 17.6% of patients), this is not an outcome that is of particular concern to acute leukemia physicians who deal with drug/disease-related neutropenia on a daily basis. Consistent with this notion, it is notable that this increased rate of neutropenia did not affect 30 day mortality rates. Indeed, the 30 day mortality rate was actually marginally higher in the placebo/LDAC arm (16%) than in the the venetoclax/LDAC arm (13%).

We would add that a neutropenia rate of 45.8% is much lower than 100% rate associated with intensive chemotherapy (IC) (see **2.i.** below).

2. Expert reviewers' comments.
We agreed with most of the reviewers' comments. For example, the experts correctly pointed out that 'venetoclax plus LDAC will likely be the treatment of choice in patients who have had prior HMA.' However, we disagree with a few key points that unfortunately seem to have featured prominently in the CADTH analysis.

2.i. Intensive chemotherapy (IC) eligibility of patients aged >75 years.
The reviewers noted correctly that some patients aged >75 years are eligible for IC. This point was subsequently used to question the pharmacoeconomic model, which did not include IC as a comparator. First, in Canada, very few patients aged >75 years receive IC. Second, the majority of such patients would have AML with favourable risk cytogenetics. Such good risk patients were not included in the VIALE-C study. Third, patients deemed ineligible for IC were specifically excluded from VIALE-C.

However, the CADTH recommendation document states that '*the cost-effectiveness of venetoclax plus LDAC compared to induction chemotherapy is unknown in patients 75 years of age and older*'. We agree, but add that the concern about IC is truly irrelevant in this context.

2.ii. Five year 'cure' assumption.
The sponsor's pharmacoeconomic analysis incorporated a cure assumption for individuals who remained in the CR/CRi health state for more than 5 years. The CADTH report states that the 'clinical experts indicated that this assumption was unlikely to be correct'. We disagree. It is standard practice to consider patients remaining in continuous CR/CRi for 5 years cured.

This question has been examined in detail (for example, see *Yanada, M et al. Potential cure of acute myeloid leukemia: Analysis of 1069 consecutive patients in first complete remission. Cancer 2007; 110:2756-2760*, or *Tamamyan, G. et al. Updated definition of cure in adult patients with non-APL acute myeloid leukemia. Clinical Lymphoma, Myeloma & Leukemia 2015; 15 Suppl. 2, S21*, among others). Hazard rates for recurrence or death in CR decline year by year post CR (and particularly after the 3rd year), with relapses becoming very, very rare after 4 years. Different cytogenetic risk groups meet cure criteria at different times. By the time the 5th year has passed, even the highest risk groups have met cure criteria.

In light of the above, the use of a '10 year cure assumption' by CADTH seems quite inappropriate.

2.ii. Prior HMA use.
While the experts correctly pointed out that 'venetoclax plus LDAC will likely be the treatment of choice in patients who have had prior HMA', they also stated that some physicians will nevertheless use Venetoclax/Azacitidine in patients who have failed/progressed on a prior HMA. While this may be true, there is no real evidence base for this approach (and certainly not evidence that CADTH would consider valid), and such patients were specifically excluded from the VIALE-A study.

Such an unsupported use of Venetoclax/Azacitidine should not contribute in any way to a decision regarding the Venetoclax/LDAC combination.

3. Other comments not attributed to the experts
Inpatient versus outpatient treatment.
The CADTH document acknowledges that *'patients expressed a desire for treatments that can be administered at home as outpatient treatment. pERC discussed that LDAC alone is administered at home and therefore addresses this patient value and further noted that unlike venetoclax plus LDAC, LDAC alone does not require hospitalization during the initial phase of treatment.'*

There are several issues here with which we disagree:

First, LDAC is often started in the inpatient setting, due to patient comorbidities, high WBC, acute leukemia-related medical issues, social issues, etc. Once a patient is stable, LDAC administration can be moved to the outpatient setting.

The blanket statement that 'LDAC alone does not require hospitalization during the initial phase of treatment' is incorrect.

Second, the notion that the venetoclax plus LDAC combination requires hospitalization during the initial phase of treatment is also incorrect. While the VIALE-C study admitted patients for the venetoclax ramp-up period, this is not required in real life practice. Venetoclax is often started in the inpatient setting, due to patient comorbidities, high WBC, acute leukemia-related medical issues, social issues, etc., but in the absence of such issues, and with the appropriate outpatient supports in place, the drug can be started safely in the outpatient setting. The Princess Margaret experience in this regard is fairly typical: <1/2 of patients are started on venetoclax in the inpatient setting (and many of these are admitted for clinical trial protocol requirement reasons).

So the notion that venetoclax must be started in the inpatient setting is incorrect (and by extension, that LDAC alone is more patient friendly, is incorrect).

4. LDAC in Canada
The role of LDAC in Canadian acute leukemia management, and the gap left by this 'Do Not Reimburse' recommendation.
The multiple compelling reasons for supporting a LDAC-based combination chemotherapy option were articulated in the initial CLSG stakeholder feedback document. We are very disappointed that the CLSG (we represent every leukemia centre in every Canadian province) opinion was not found to be compelling.

To reiterate briefly…
The relative merits/disadvantages of LDAC (compared to a HMA) are well known to physicians treating AML, as we have used LDAC (and HMAs) for many years. As acknowledged in the CADTH document, LDAC is advantageous for several reasons, including geography, travel, homecare administration,

fewer clinic visits, prior HMA etc. considerations, among others. These considerations are particularly important in Canada (centralized acute leukemia care requiring considerable patient/caregiver travel), and during the COVID-19 pandemic.

LDAC as a single agent has limited efficacy. The addition of Venetoclax or of Glasdegib to LDAC (the latter drug was actually proved effective in a randomized trial, but nevertheless was not recommended for reimbursement) both improve the efficacy of LDAC with respect to response and survival. Canadian patients with AML require a LDAC-based option. In contrast to what is suggested in the CADTH recommendation document, LDAC alone is not a suitable option. The absence of an LDAC-based, non-HMA combination option leaves a huge gap in Canadian leukemia care. We believe that the combination of venetoclax with LDAC addresses this need.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation? NOT APPLICABLE	Yes	☐
	No	☐
If not, please provide details regarding the information that requires clarification. **NOT APPLICABLE**		

[a] CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒

If yes, please list the clinicians who contributed input and whose declarations have not changed:

- Yasser Abou Mourad (Vancouver)
- Lynn Savoie (Calgary)
- Joseph Brandwein (Edmonton)
- Waleed Sabry (Saskatoon)
- Kristjan Paulson (Winnipeg)
- Lalit Saini (London)
- Brian Leber (Hamilton)
- Andre Schuh (Toronto)
- John Storring (Montreal)
- Julie Bergeron (Montreal)

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Please state full name*

Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2

Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3

Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 4	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0239-000
Brand name (generic)	Venclexta (venetoclax) – AbbVie
Indication(s)	Manufacturer Requested Reimbursement Criteria: In combination with low-dose cytarabine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
Organization	Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee (Hem DAC)
Contact information[a]	Name: Dr. Tom Kouroukis Email: [redacted] Phone:

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. Clinicians and patients would have preferred an LDAC-based option with venetoclax. Therefore there is no venetoclax-based option for patients previously treated with HMA for MDS.		

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐
If not, what aspects are missing from the draft recommendation?		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☐
If not, please provide details regarding the information that requires clarification. Not applicable.		
	Yes	☐

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	No	☐
If not, please provide details regarding the information that requires clarification. Not applicable		

[a] CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.

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A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
If yes, please detail the help and who provided it. OH-CCO provided secretariat support to the DAC in completing this form.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Tom Kouroukis • Dr. Pierre Villeneuve • Dr. Lee Mozessohn • Dr. Jordan Herst • Dr. Janet MacEachern (DAC term completed in March 2021) • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*

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Conflict of Interest Declaration

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
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Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
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Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

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Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
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Date	*Please add the date form was completed (DD-MM-YYYY)*
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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0239
Name of the drug and Indication(s)	Venetoclax in combination with low-dose cytarabine for AML
Organization Providing Feedback	PAG

1. Recommendation revisions
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.

Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	☐
	No requested revisions	x

2. Change in recommendation category or conditions
Complete this section if major or minor revisions are requested

None.

3. Clarity of the recommendation
Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

None.

b) Reimbursement conditions and related reasons

None.

c) Implementation guidance

None.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0239-000
Brand name (generic)	Venetoclax (Venclexta)
Indication(s)	In combination with low dose cytarabine for the treatment of patients with newly diagnosed AML who are 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy
Organization	The Leukemia & Lymphoma Society of Canada (LLSC)
Contact information[a]	Name: Indrek Koppel Email: [redacted] Phone: [redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☐
	No	☒

Firstly, we would like to extend our thanks to the committee for recognizing the unmet need for better AML treatment options with their positive reimbursement recommendation of venetoclax plus azacitidine.

With that said, we respectfully disagree with the committee's do not reimburse recommendation of venetoclax + low dose cytarabine. We feel that there is a strong need for additional AML treatment options:

1) that can be safely administered at home or in a community setting
2) for patients who progressed from MDS
3) for patients with a history of receiving a hypomethylating agent

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

If not, what aspects are missing from the draft recommendation?

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

	Yes	☒

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	No	☐
If not, please provide details regarding the information that requires clarification.		

[a] CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Indrek Koppel*
Position	*Manager, Advocacy & Partnerships*
Date	*22-07-2021*
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
	☐	☐	☐	☐