CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

TECLISTAMAB (Tecvayli)

(Janssen Inc.)

Indication: For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

March 22, 2024

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0332
Brand name (generic)	Tecvayli (teclistamab)
Indication(s)	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy
Organization	Hematology Cancer Drug Advisory Committee
Contact information[a]	Name: Dr. Tom Kouroukis

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. Patients with plasma cell leukemia should be eligible for teclistamab despite being excluded from the trial. Despite lack of evidence, there should be an allowance for teclistamab after CAR-T cell therapy or following other anti-BCMA therapies.		

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. Adequately equipped systemic therapy centres should be able to provide teclistamab provided they have the necessary education for toxicity management as well as tocilizumab availability. Although patients may need to travel for this treatment, they should not need to go out of province.		

There may be value in giving tocilizumab prophylactically to some patients to avoid hospital admission.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		

[a] CADTH may contact this person if comments require clarification.

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - 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. OH (CCO) provided a secretariat function to the group.		
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		

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	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0332-000
Brand name (generic)	Tecvayli
Indication(s)	Relapsed or refractory multiple myeloma
Organization	The Canadian Myeloma Research Group
Contact information[a]	Name: Donna E Reece,MD

Stakeholder agreement with the draft recommendation

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

Bispecific and CAR-T cell therapies are presently positioned to address the unmet need in the "triple-class exposed/refractory" myeloma patients. Like the recently endorsed product cilta-cel, the latest data for teclistamab are expected to exceed that of any previous standard of care regimen for this group of "triple-class refractory" patients. Teclistamab also addresses the myeloma in an entirely novel way, thus overcoming resistance mechanisms to the more traditional approved approaches. Currently, it would be used in sequence after the other lines of therapy described in Section 3. per the available information from CADTH

As there are very few options in patients with triple-class refractory disease, the issue of intolerance to other treatments or contraindications to other treatments is less relevant. Specifically, all other options that are currently available in this setting yield markedly inferior results.

As teclistamab will be used late in the current lines of myeloma treatment, i.e. after failure of multiple agents, it is not expected to impact the sequencing of agents earlier in the disease course, or lead to a major change in treatment algorithms prior to patients becoming "triple-class exposed/refractory". However, given its impressive efficacy in terms of both a high response rate and durability of response, it is expected to lead to a major shift in the current treatment paradigm for those with advanced disease. It will provide an additional, more readily accessible T-cell redirecting therapy for patients refractory to the most commonly used agents. Availability of teclistamab will complement access to the recently endorsed cilta-cel T-cell platform, broadening access to such new therapeutic strategies, and ensuring that logistical bottlenecks do not become a barrier for delivery of these novel products to Canadian patients.

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.

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

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.
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  - 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: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Donna Reece*
Position	*Chief Medical Officer, CMRG*
Date	*(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.

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 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				
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.				
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	$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 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

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 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

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	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0332-000
Brand name (generic)	Tecvayli
Indication(s)	Relapsed or refractory multiple myeloma
Organization	The Canadian Myeloma Research Group
Contact information[a]	Name: Donna E Reece,MD

Stakeholder agreement with the draft recommendation

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

Bispecific and CAR-T cell therapies are presently positioned to address the unmet need in the "triple-class exposed/refractory" myeloma patients. Like the recently endorsed product cilta-cel, the latest data for teclistamab are expected to exceed that of any previous standard of care regimen for this group of "triple-class refractory" patients. Teclistamab also addresses the myeloma in an entirely novel way, thus overcoming resistance mechanisms to the more traditional approved approaches. Currently, it would be used in sequence after the other lines of therapy described in Section 3. per the available information from CADTH

As there are very few options in patients with triple-class refractory disease, the issue of intolerance to other treatments or contraindications to other treatments is less relevant. Specifically, all other options that are currently available in this setting yield markedly inferior results.

As teclistamab will be used late in the current lines of myeloma treatment, i.e. after failure of multiple agents, it is not expected to impact the sequencing of agents earlier in the disease course, or lead to a major change in treatment algorithms prior to patients becoming "triple-class exposed/refractory". However, given its impressive efficacy in terms of both a high response rate and durability of response, it is expected to lead to a major shift in the current treatment paradigm for those with advanced disease. It will provide an additional, more readily accessible T-cell redirecting therapy for patients refractory to the most commonly used agents. Availability of teclistamab will complement access to the recently endorsed cilta-cel T-cell platform, broadening access to such new therapeutic strategies, and ensuring that logistical bottlenecks do not become a barrier for delivery of these novel products to Canadian patients.

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	☐

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.

There are several pilot programs in Canada that are evaluating the initiation of teclistamab, including step-up dosing, in the outpatient setting. This is being conducted with strict protocols for management

of complications such as fever, CRS, neurologic toxicity and infection as well as immediate inpatient admission for patients meeting pre-defined criteria. Thus, the teclistamab initiation guidelines may evolve as experience with this agent increased.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		

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A. Patient Group Information	
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 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**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - 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: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

Declaration for Clinician 1

Name: Dr. Darrell White

Position: Hematologist, Dalhousie University and QEII Health Sciences Centre

Date: 08-09-2023

☒ 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.

Table 1: Conflict of Interest Declaration for Clinician 1

Company	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
BMS		X		
Janssen			X	

Declaration for Clinician 2

Name: Dr. Alexander Keith Stewart

Position: Professor, Division of Hematology-Oncology Princess Margaret Cancer Centre

Date:08-09-2023

☒ 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.

Table 2: Conflict of Interest Declaration for Clinician 2

Company	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen			X	
Amgen		X		
Pfizer	X			
Sanofi	X			
GSK	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Dr. Stephen Parkin

Position: Hematologist, Clinical Assistant Professor

Date: 08-09-2023

☒ 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.

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen (speaker, consultancy fees)	X			
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: Dr. Jason Hart

Position: Medical oncologist and hematologist, BC Cancer, Victoria

Date: 08-09-2023

☒ 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.

Table 4: Conflict of Interest Declaration for Clinician 4

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: Dr. Annette Hay

Position: Professor, Queen's University, Head, Division of Hematology, Kingston Health Sciences Centre

Date: 08-09-2023

☒ 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.

Table 5: Conflict of Interest Declaration for Clinician 5

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Roche				X
Merck				X
Seattle Genetics				X
Abbvie				X
Incyte				X
Janssen				X
Karyopharm				X

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Dr. Donna Reece

Position: Chief Medical Officer, CMRG

Date: 08-09-2023

☒ 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.

Table 6: Conflict of Interest Declaration for Clinician 6

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
BMS/ Celgene			X	
Janssen			X	
Amgen			X	
Sanofi	X			
GSK	X			
Takeda	X			

Declaration for Clinician 7

Name: Dr. Anthony Reiman

Position: Professor, Department of Oncology, Saint John Regional Hospital

Date: 08-09-2023

☒ 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.

Table 7: Conflict of Interest Declaration for Clinician 7

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Nothing to Declare				

Declaration for Clinician 8

Name: Dr. Heather Sutherland

Position: Hematologist, Vancouver General Hospital

Date: 09-09--2023

☒ 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.

Table 8: Conflict of Interest Declaration for Clinician 8

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Forus	X			

Declaration for Clinician 9

Name: Dr. Hira Mian

Position: Assistant Professor

Date: 09-09-2023

☒ 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.

Table 9: Conflict of Interest Declaration for Clinician 9

Company	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Takeda, Jansen, BMS, Sanofi, Amgen, GSK (advisory board fees)		X		
Jansen Research Funding				X
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 10

Name: Dr. Richard LeBlanc

Position: Hematologist and medical oncologist

Date: September 9th 2023

☒ **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.

Table 10: Conflict of Interest Declaration for Clinician 10

Company	Check appropriate dollar range*

	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Janssen – advisory boards and honoraria		X		
Pfizer – advisory board and honoraria		X		
BMS – advisory boards	X			
Amgen – advisory boards	X			
Sanofi – advisory boards	X			
FORUS Therapeutics – advisory boards	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 11

Name: Dr. Arleigh Mccurdy

Position: Hematologist, Oncologist

Date: 09-09-2023

☒ 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.

Table 11: Conflict of Interest Declaration for Clinician 11

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
BMS/Celgene	X			
Takeda	X			
Amgen	X			
Janssen	X			
Sanofi	X			

Forus Therapeutics	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 12

Name: Dr. Christopher Venner

Position: Hematologist Lymphoma and Myeloma Program, BC Cancer Vancouver Centre

Date: 11-10-2022

☒ 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.

Table 12: Conflict of Interest Declaration for Clinician 12

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Celgene/BMS	X			
Takeda	X			
Janssen	X			
Amgen	X			
Sanofi	X			
GSK	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 13

Name: Dr. Jean Roy

Position: Full professor, Université de Montréal, hematologist, Maisonneuve-Rosemont Hospital

Date: 11-09-2023

☒ 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.

Table 13: Conflict of Interest Declaration for Clinician 13

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 14

Name: Dr. Sita Bhella

Position: Hematologist, Princess Margaret Cancer Centre

Date: 11-09-2023

☒ 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.

Table 14: Conflict of Interest Declaration for Clinician 14

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Gilead	X			
Novartis	X			
Sanofi	X			
Amgen	X			
Celgene/Bristol Myers Squibb	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 15

Name: Dr. Victor Zepeda

Position: Hematologist, Oncologist

Date: 11-09-2023

☒ 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.

Table 15: Conflict of Interest Declaration for Clinician 15

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Janssen		X		
BMS	X			
Takeda	X			
Amgen	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 16

Name: Dr. Sindu Kanjeekal

Position: Hematologist, Oncologist

Date: 11-09-2023

☒ 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.

Table 16: Conflict of Interest Declaration for Clinician 16

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 17

Name: Dr. Kevin Song

Position: Hematologist, Vancouver General Hospital

Date: 11-09-2023

☒ 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.

Table 17: Conflict of Interest Declaration for Clinician 17

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Bristol Myers Squibb		X		
Janssen		X		
Amgen		X		

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 18

Name: Dr. Nizar A. Samad

Position: MD Hematology

Date: 14-09-2023

☒ 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.

Table 18: Conflict of Interest Declaration for Clinician 18

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 19

Name: Dr. Sathish Gopalakrishnan

Position: Oncologist and Hematologist

Date: 14-09-2023

☒ 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.

Table 19: Conflict of Interest Declaration for Clinician 19

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**

Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 20

Name: Dr. Rami Kotb

Position: Hematologist, Oncologist, Cancer Care Manitoba

Date: 14-09-2023

☒ 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.

Table 20: Conflict of Interest Declaration for Clinician 20

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
BMS, Amgen, JNJ		X		
Takeda	X			
Sanofi, Merck				X
Karyopharm				X

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 21

Name: Dr. Michael Pavic

Position: Hematologist

Date: 14-09-2023

☒ 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.

Table 21: Conflict of Interest Declaration for Clinician 21

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				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 22

Name: Dr. Marc Lalancette

Position: Hematologist

Date: 14-09-2023

☒ 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.

Table 22: Conflict of Interest Declaration for Clinician 22

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 23

Name: Dr. Suzanne Trudel

Position: Oncologist

Date: 14-09-2023

☒ 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.

Table 23: Conflict of Interest Declaration for Clinician 23

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Sanofi	X			
BMS			X	

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 24

Name: Dr. Nicole Laferriere

Position: Hematologist/ Chief of Oncology

Date: 14-09-2023

☒ 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.

Table 24: Conflict of Interest Declaration for Clinician 24

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Astra Zeneca, AMGEN Canada, ROCHE, Abbvie, Sanofi Canada, Lundbeck, Janssen, Celgene, Teva	X			

Pharm, Novartis, KiTE, AbbVie, Incyte				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 25

Name: Dr. Alfredo de la Torre

Position: Hematologist

Date: 14-09-2023

☒ 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.

Table 25: Conflict of Interest Declaration for Clinician 25

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Nothing to declare				

* Place an X in the appropriate dollar range cells for each company.

New or Updated Declaration for Clinician 26	
Name	Alissa Visram
Position	Physician, The Ottawa Hospital
Date	20/03/2025
X	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
Janssen	X	☐	☐	☐
Pfizer	X	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation - Tecvayli

Stakeholder information	
CADTH project number	PC0332-000-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Tecvayli (teclistamab)
Indication(s)	Relapsed or refractory multiple myeloma
Organization	Myeloma Canada
Contact information	Aidan Robertson

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

Myeloma Canada is pleased that pERC has decided to recommend the reimbursement (with conditions) of teclistamab. While Myeloma Canada agrees with the approval recommendations given the concerns noted in the review, we do not agree with the conditionality of the price reduction at the recommended 89%. We think this is unreasonably high and may serve to curtail patient access. Though the evidence remains limited, and the implementation concerns are notable, access to this novel therapy is a critical step towards meeting the need for effective myeloma treatments in the fourth-line setting (and beyond).

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?

Yes, the review demonstrates that the committee has considered Myeloma Canada's stakeholder input. Though we would note that on page 8 the final paragraph under Patient Group Input inaccurately represents the information provided to CADTH. It should read: "*From August 28 to September 30, 2022, Myeloma Canada also conducted a different survey about a CAR T-cell therapy which received over 200 responses, only 2 of which had experience with the CAR T-cell therapy, while our teclistamab survey received far fewer (33) total responses, there were 11 patients with teclistamab experience. Myeloma Canada emphasized that this is indicative of the comparative ease with which teclistamab can and has been made accessible to Canadians with triple-class exposed RRMM.*"

As well, only eligible patient responses were represented, not the experiences of patients who had received/were receiving teclistamab. We feel patient experience with the drug under review is a crucial component of our input and one of few opportunities the pERC has to hear from patients and caregivers (in their own words) how teclistamab treatment has impacted them. We hope these experiences were read and considered in the review.

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.
Yes, we feel the reasons are largely clearly stated.

We feel additional clarification is needed on why, considering the uncertainty in sequencing of teclistamab, the comparator of physician's choice was seen to be more appropriate than cilta-cel, and what the necessary cost reduction would be if cilta-cel were used. We also agree with the pERC's assertion that neither comparators (physicians choice & cilta-cel) are ideal. Considering there are currently two additional bispecific antibodies for the treatment of myeloma at different stages of the reimbursement review process with CADTH (elranatamab, talquetamab), if these treatments are recommended for reimbursement, we expect they would be better comparators for teclistamab, and that the price adjustment would require recalculation at this point (before these drugs are sequenced).

The pERC noted clinical experts felt that "*…patients who are resistant or intolerant to a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody should be eligible to receive teclistamab at the point that these therapies are no longer effective or appropriate regardless of what line of therapy it is in.*" Myeloma Canada completely agrees with this point, considering the increasing use of combination therapies at earlier lines (particularly for transplant ineligible patients), there are more and more patients who find themselves in the above situation. We think these patients should be included in the recommendation, and would appreciate clarification from the pERC on why this was not the case.

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.

Upon review by patient members of the Myeloma Canada National Advocacy Committee, a patient currently receiving treatment with teclistamab noted they felt *"..the implementation issues have been clearly articulated… and they appear to be adequately addressed."*
Where teclistamab may fall in the sequencing algorithm for R/R MM will be critical for ensuring Canadian patients have timely access to effective treatments at the fourth line or later, particularly considering the serious implementation issues with cilta-cel.

Though we understand based on current efficacy comparisons and other differences, why teclistamab may not displace cilta-cel in the algorithm if funded, we would want to stress that considering the far more significant implementation issues with cilta-cel, the algorithm must inhere enough flexibility to ensure patients have timely access to treatment, which will likely be dependent on which is most readily available to them— not on which treatment is sequenced first. On this note, we would recommend that CADTH works to publish proposed/recommended changes to sequencing algorithms along with, or immediately following draft recommendations in the future. This information would be valuable to provinces in the pCPA negotiation process, and help expediently inform policy decisions encourage alignment in sequencing across jurisdictions.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

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

We acknowledge the pERC felt there was currently insufficient evidence to support teclistamab in patients previously treated with BCMA targeted therapies, nor biweekly dosing of teclistamab (in patients achieving a certain level of response), though we would note that providing physicians the flexibility to treat patients in these smaller cohorts, may aid in generating the real-world data necessary to illuminate the efficacy in these populations. The number of Canadian patients previously treated with BCMA targeted therapies is likely very small, and their treatment options are equally extremely limited considering so many of the newest treatments for mm available to Canadians are BCMA targeted (idecel, cilta-cel, blenrep, teclistamab, elranatamab, linvoseltamab, etc…), and they are currently largely used in later lines of therapy (fourth-line and beyond), meaning these patients will have *zero* options funded at the fourth line or later. We feel the pERC should reconsider its recommendation in this context.
Similarly, we hope that if additional supporting evidence on biweekly dosing becomes available, the pERC's position on these issues will be amended— in which case we would feel it necessary for the price reduction conditions to be recalculated based on both the reduction in healthcare resource utilization costs, and potential improvement in quality of life for patients.

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21 March 2024

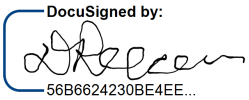
RE: CMRG feedback on Draft Recommendation for TECVAYLI (teclistamab)
(CADTH project PC0332-000)

Dear CADTH members:

On behalf of the CMRG, please find our feedback on the proposed recommendations for teclistamab reimbursement. This document represents the consensus opinion that was endorsed by each of the physicians listed on the document.

Thank you for the opportunity to review this draft. Please feel free to contact me for any questions.

With regards,



Donna E. Reece, MD
Chief Medical Officer
Canadian Myeloma Research Group (CMRG)

Professor of Medicine
Princess Margaret Cancer Centre

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0332
Name of the drug and Indication(s)	Teclistamab injection is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.
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	X
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons

Please provide details regarding the information that requires clarification. - Under considerations for initiation of therapy, PAG is requesting clarification on the use of teclistamab if patients received prior BCMA-targeted therapy and on the use of CAR-T cell therapy post teclistamab. - Under considerations for initiation of therapy, PAG suggests the HC indication and manufacturer request for the use of teclistamab after 3 prior lines be added after the following statement: "There is no evidence reviewed to inform this." - Under considerations for prescribing of therapy, PAG suggested changing the following statement to "first 2-3 doses" for more flexibility as long as this is in agreement with the drug monograph: pERC acknowledged that the clinical experts noted that patients starting treatment with teclistamab will receive first 2 doses in the hospital… - Under Generalizability, PAG would like to clarify whether the drug can be used for plasma cell leukemia and amyloidosis without multiple myeloma.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. The algorithm will need to be updated (after elranatamab recommendation is available). 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?

May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0332-000
Brand name (generic)	TECVAYLI™ (teclistamab)
Indication(s)	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy
Organization	Janssen Inc.
Contact information[a]	[redacted]

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

Janssen agrees with the committee's recommendation. As stated in the recommendation, patients identified a need for accessible and effective treatment options, beyond third line, that delay disease progression, prolong survival, improve quality of life, and have manageable side effects with ease of administration. Janssen agrees with the clinical experts and pERC committee that the overall response rate and complete response rate in the MajesTEC-1 trial were clinically meaningful and that the overall survival and progression-free survival results were promising. Janssen also agrees that there was consistency in the direction of effects favouring teclistamab over real-world physician's choice therapy across the outcomes assessed, including clinical responses, OS, and PFS.

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	☐

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☐

For the Discussion Points listed below related to implementation and delivery of teclistamab, Janssen has provided additional context.

1) pERC discussed the implementation of teclistatamab, stating that "Teclistamab must be administered at specialized treatment centres with the infrastructure and resources required

to administer the treatment and manage adverse events. However, a limited number of centres in Canada have the expertise and resources to deliver teclistamab and other CRS and ICANS management as needed, and it is unlikely that qualified centres will be available in all jurisdictions" (pg. 6).

In alignment with the product monograph and the reimbursement conditions in the CADTH recommendation, "Teclistamab should be administered by health professionals at treatment centres with adequate medical resources and personnel to manage severe reactions, including cytokine release syndrome and neurologic toxicities." However, this does not mean that a specialized treatment centre is required for the administration of teclistamab, and it is expected that teclistamab will be administered in various community oncology settings. Janssen expects that there will be differences across jurisdictions, hospitals, and health professionals and the administration of teclistamab will be at the discretion of each institution based on their experience and resources.

2) pERC discussed that some patients in the MajesTEC-1 trial switched from a weekly to a biweekly or monthly dosing schedule and concluded that there is limited evidence that switching teclistamab to every 2 weeks or monthly dosing is as effective as teclistamab taken weekly (pg. 5).

   Janssen would like to note that currently there is more evidence supporting the biweekly dosing schedule compared to the monthly schedule and the biweekly dosing schedule is under review at Health Canada.

3) The clinical experts involved in the review indicated that patients starting treatment with teclistamab will receive first 2 doses in the hospital, and after that they can safely receive ongoing therapy in an outpatient setting on a case-by-case basis (pg. 6).

   Janssen would like to note that while hospitalization for step-up dosing may be the approach that is currently preferred by clinicians, it is not a requirement as per the Health Canada product monograph and is subject to change as clinicians gain experience with treating patients with teclistamab. Monitoring requirements in the product monograph state: "Instruct the patients to remain within proximity of a healthcare facility and monitor daily for 48 hours for signs and symptoms of CRS after administration of all doses within the Tecvayli step-up dosing schedule, or alternatively consider hospitalization for patients." Therefore, hospitalization for step-up dosing will be at the discretion of the hospitals and clinicians delivering teclistamab based on their experience and resources.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☐

For the reimbursement conditions described below, Janssen has provided additional feedback and context related to implementation of the conditions in clinical practice.

1) **ECOG Performance Status:** Regarding the implementation guidance provided for reimbursement condition 1.5 (patients must have good performance status) stating that "pERC acknowledged that clinicians may consider using teclistamab for patients with an ECOG performance status ≥ 2 at their discretion (pg. 4), Janssen agrees that clinicians should be able to use their discretion when assessing a patient's eligibility for teclistamab based on performance status and not be limited by the MajesTEC-1 trial criteria of ECOG status 0 or 1.

2) **Management of Adverse Events:** Regarding the implementation guidance for reimbursement condition 4 (related to management of adverse events), it was stated that "pERC recognized that access to tocilizumab for the treatment of cytokine release syndrome is necessary" (pg. 4). In addition, one of the Discussion Points stated, "pERC noted that the adverse events in the MajesTEC-1 study were manageable, however access to supportive treatments for adverse events is needed (e.g., tocilizumab to treat cytokine release syndrome of any grade)" (pg.6).

Janssen would like to note that this may not be reflective of clinical practice, as tocilizumab may not be required for all patients who experience cytokine release syndrome (CRS). For management of CRS of Grade 2 or higher, the Health Canada product monograph for teclistamab states to "administer tocilizumab", while for Grade 1 CRS, the product monograph states that tocilizumab "may be considered," therefore management should be specific to each individual patient.

[a] CADTH may contact this person if comments require clarification.

Sponsor's References

1. Janssen Inc. Health Canada Product Monograph for TECVAYLI™(Teclistamab injection) 2023.