Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC PROVISIONAL FUNDING ALGORITHM

Input on Project Scope from External Partners

Multiple Myeloma

Jan 10, 2025

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings. **If your group has submitted input that is not reflected within this document, please contact Pharmaceuticals@cda-amc.ca.**

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

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

CDA-AMC 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 group and all conflicts of interest information from individuals who contributed to the

Input on Proposed Scope for Provisional Funding Algorithm

Patient, Clinician, or Industry Group Information

Project number: PH0068-000

Condition (or indication) under review: Multiple Myeloma

Organization name: Janssen Inc.

Contact information (if comments require clarification)

Full name: [redacted]

Current position: Associate Director, HTA Submissions and Analytics, Market Access

Email: [redacted]

Phone: [redacted]

Contact information will not be included in any public posting of this document.

For Both Rapid and Panel Provisional Funding Algorithms (Required)

Q1: Based on the proposed scope of the provisional funding algorithm, the other drugs that could be impacted, and the current reimbursement setting, what factors do you think should be considered in the development of the provisional funding algorithm? Please provide your input:

Factors that should be considered in the development of the provisional funding algorithm:

- Therapies not listed as in scope which may be relevant to appropriately address question:
    - Talquetamab, pending the outcome of the CDA reconsideration due to its potential for use in patients with RRMM who have received prior BCMA-directed therapy
    - Belantamab mafodotin, a BCMA-targeting therapy, due to its usage in Canadian patients through clinical trials/early access and impact on the number of BCMA-exposed patients in Canada and submissions received by CDA in December 2024
- Data on sequencing of different treatment options following treatment with a BCMA-directed therapy, including clinical outcomes for patients after subsequent therapy post-

treatment with BCMA-directed therapy [e.g., treatment with pomalidomide + dexamethasone ± cyclophosphamide (P(C)d), carfilzomib + dexamethasone ± cyclophosphamide (K(C)d), another BCMA-directed therapy, or treatment with another novel agent with a different target (GPRC5D/talquetamab pending outcome of CDA recommendation)]

- Data on sequencing related to each individual treatment (i.e., teclistamab, elranatamab, ciltacabtagene autoleucel) to have specific guidance for each treatment versus BCMA-targeted treatment as a whole
- Retreatment with BCMA-directed therapy including outcomes and timing of treatment (e.g., immediately following prior BCMA-directed therapy versus after receiving therapy with a different and then returning to a BCMA-directed therapy)
- Availability, accessibility and patient criteria for BCMA treatment options and post-BCMA treatment options in Canada and the impact on treatment options (e.g., CDA Provisional Funding Algorithm specifies that patients who have received a prior treatment with any therapy that targets BCMA cannot receive CARVYKTI® (ciltacabtagene autoleucel) or elranatamab subsequently)
- Data and clinical input on the impact of switching from a BCMA-directed therapy to a different therapy with a different target for subsequent treatment (i.e., impact on response to treatment)

Recommendations for panelists based on relevant expertise in the diagnosis and management of the condition and knowledge about the question:

- [redacted] (hematologist/oncologist, [redacted])
  [redacted]
- [redacted] (hematologist/oncologist, [redacted])
  [redacted]
- [redacted] (hematologist/oncologist, [redacted])
  [redacted]

Specific evidence that the panel may consider are listed below:

1) Mian HH, J.; Le, H.; Fu, A. Real-world Treatment Patterns and Clinical Outcomes among Triple-class Exposed and B-cell Maturation Antigen (BCMA) Exposed Multiple Myeloma Patients. Paper presented at: 65th American Society of Hematology (ASH) Annual Meeting; December 9-12, 2023; San Diego, CA, USA.
2) Sharma R, Paul P, Masih-Khan E, et al. Outcomes of Relapsed/Refractory Multiple Myeloma Patients Receiving Sequential Therapies after Exposure to T-Cell Redirected or BCMA-Targeted Novel Immunotherapies. Blood. 2024;144(Supplement 1):1956-1956.
3) Quach H. Reengaging life post-BCMA for myeloma. Blood. 2024;144(23):2365-2367.

Studies on talquetamab outcomes post BCMA (MonumenTAL-1, Cohort B)

4) Mateos MVJ, A.; Einsele, H.; et al. Talquetamab vs Real-World Physician's Choice in Patients With Relapsed/Refractory Multiple Myeloma and Prior B-Cell Maturation Antigen Therapy: Analyses of MonumenTAL-1 vs LocoMMotion/MoMMent. Paper presented at: 21st International Myeloma Society (IMS) Annual Meeting; September 25–28, 2024; Rio de Janeiro, Brazil.
5) Rasche LS, C.; Touzeau, C.; et al. Long-Term efficacy and Safety Results From the Phase 1/2 MonumenTAL-1 Study of Talquetamab, a GPRC5D×CD3 Bispecific Antibody, in Patients With Relapsed/Refractory Multiple Myeloma. Paper presented at: Presented by L Rascheat the European Hematology Association (EHA) 2024 Hybrid Congress; June 13–16, 2024; Madrid, Spain.

Studies on ciltacabtagene autoleucel outcomes post BCMA, time from prior BCMA, and subsequent therapy post ciltacabtagene autoleucel

6) Cohen AD, Mateos MV, Cohen YC, et al. Efficacy and safety of cilta-cel in patients with progressive multiple myeloma after exposure to other BCMA-targeting agents. Blood. 2023;141(3):219-230.
7) Sidana S, Patel KK, Peres LC, et al. Safety and efficacy of standard-of-care ciltacabtagene autoleucel for relapsed/refractory multiple myeloma. Blood. 2025;145(1):85-97.
8) Jiang Y, Gao W, Zhu H, Chen W. Outcome in Patients with Multiple Myeloma Receiving Salvage Therapy after Exposure to BCMA-Targeted CAR-T Therapy. Blood. 2024;144(Supplement 1):7087-7087.

For Panel Provisional Funding Algorithm Only (Not Required for Rapid Provisional Funding Algorithm)

Q2: Based on the implementation issues described in the proposed scope, what implementation issues could be addressed by the panel? Please provide your input:

- The impact of an expanding patient population that is BCMA exposed (e.g., unmet need for non-BCMA treatment options due to the lack of options)
- Optimal sequencing for teclistamab, elranatamab, and ciltacabtagene autoleucel including nuances based on prior therapy (exposure), refractory status, patient characteristics, eligibility criteria/conditions in Canada, toxicity

Q3: Are there any implementation issues that may not have been addressed in the proposed scope? Please provide your input:

- Therapies not listed as in scope as stated above

Appendix 1: Conflict-of-Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the 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 input from patient groups.
- We may contact your group with further questions, as needed.

A. Patient Group Information

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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

Did you receive help from outside your patient group to complete your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

Did you receive help from outside your patient group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

C. New or Updated Conflict-of-Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 1: Conflict-of-Interest Declaration for Patient Group

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Appendix 2: Conflict-of-Interest Declarations for Clinician Groups

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- For conflict-of-interest declarations:
  - list any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review
  - provide declarations for each clinician that contributed to the input
  - include only new conflict-of-interest declarations or ones that require updating if your clinician group provided input at the beginning of the outset of the review; for all others, please list the clinicians whose provided input is unchanged
  - add more tables as needed (copy and paste)
  - include all new and updated declarations in a single document.

A. Assistance With Providing the Feedback

Did you receive help from outside your clinician group to complete your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

Did you receive help from outside your clinician group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

B. Conflict-of-Interest Declarations

List any companies or organizations that have provided your group or member(s) of your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review. This is required for each clinician that contributed to the input — please add more tables as needed (copy and paste). It is preferred that all declarations be included in a single document.

Declaration for Clinician 1

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 2: Conflict-of-Interest Declaration for Clinician 1

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Declaration for Clinician 2

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 3: Conflict-of-Interest Declaration for Clinician 2

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 3

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 4: Conflict-of-Interest Declaration for Clinician 3

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 4

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 5: Conflict-of-Interest Declaration for Clinician 4

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 5

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 6: Conflict-of-Interest Declaration for Clinician 5

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Input on Proposed Scope for Provisional Funding Algorithm

Patient, Clinician, or Industry Group Information

Project number: PH0068-000

Condition (or indication) under review: Multiple Myeloma

Organization name: Myeloma Canada

Contact information (if comments require clarification) Full name: Aidan Robertson

Current position: Health Policy and Advocacy Advisor

Email: [redacted]

Phone: [redacted]

Contact information will not be included in any public posting of this document.

For Both Rapid and Panel Provisional Funding Algorithms (Required)

Q1: Based on the proposed scope of the provisional funding algorithm, the other drugs that could be impacted, and the current reimbursement setting, what factors do you think should be considered in the development of the provisional funding algorithm? Please provide your input:

- **Individualized Treatment Beyond the Fourth Line:** If this review focuses specifically on the initial fourth-line indications for treatments under review (ciltacabtagene autoleucel, elranatamab, teclistamab), defining optimal subsequent treatments becomes highly case-dependent. Myeloma is a uniquely complex disease, with patients' treatment histories varying more greatly with each line of therapy. By the fourth line, factors such as treatment resistance, overall health, and disease characteristics significantly limit options. Any proposed treatment algorithm must strive to avoid imposing additional constraints on these patients' treatment options.
- **Unmet Needs for Relapsed/Refractory Myeloma:** Relapsed refractory myeloma, particularly following BCMA-directed therapy at the fourth line, remains a significant unmet need.
- **Potential for Sequential BCMA-Directed Therapies:** Preliminary studies have shown that BCMA directed therapies with different mechanisms of action can be successful in the same patient and pointed to the length of time between these treatments as a potential factor in their success. Particularly with the recent expansion of ciltacabtagene autoleucel's indication, if patients receive ciltacabtagene autoleucel as early as first relapse, they in fact may be good candidates for subsequent treatment with teclistamab or elranatamab at a later line of therapy. Similarly, many Canadian patients are receiving BCMA-directed treatments through clinical trials at earlier lines of therapy. These patients should be taken into consideration in the algorithm's development.

For Panel Provisional Funding Algorithm Only (Not Required for Rapid Provisional Funding Algorithm)

Q2: Based on the implementation issues described in the proposed scope, what implementation issues could be addressed by the panel? Please provide your input:

Click here to provide your input

- **Flexibility within the Algorithm:** It is essential to ensure flexibility in treatment algorithms to account for patient heterogeneity. Clinicians must have the autonomy to make treatment recommendations based on their expertise and the unique needs of their patients.
- **Restrictions on Re-treatment:** Some drug programs prohibit patients from receiving the same treatment twice, even if they were not refractory to it. Such restrictions may further limit treatment options available to patients and their clinicians after BCMA-directed therapy.
- **Challenges for Heavily Pre-treated Patients:** Patients who receive triplet or quadruplet therapies as initial treatment (with or without autologous stem cell transplant [ASCT) are increasingly likely to become triple-class exposed or refractory after one or two lines of therapy. These patients typically have less favorable outcomes with standard treatments and urgently need new therapies with novel cellular targets or mechanisms of action. Yet, anti-BCMA targeted therapies are largely only approved at the fourth line of treatment, meaning patients may be forced to receive a less effective treatment first, leaving them in poorer health and less likely to benefit from subsequent BCMA therapy. It is critical to ensure patients have access these therapies at a stage when they can derive the greatest benefit, particularly given the high cost of BCMA-targeted agents, and the limited effective subsequent treatment options.

Q3: Are there any implementation issues that may not have been addressed in the proposed scope? Please provide your input:

- **Impact of CAR T Logistical Issues:** The differing accessibility and implementation issues facing CAR T-cell therapy versus bispecific antibodies have been widely identified and described by CDA in many algorithms and reimbursement reviews. This algorithm must strive to ensure its advice can be useful, and practically applied in light of these issues, or include qualifications to its recommendations to account for scenarios in which it may not be possible to follow the panel's advice, for example, due to the availability of/lack of access to ciltacabtagene autoleucel.

Appendix 1: Conflict-of-Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the 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 input from patient groups.
- We may contact your group with further questions, as needed.

A. Patient Group Information

Full name: Aidan Robertson

Current position: Health Policy and Advocacy Advisor

Date form completed (dd-mm-yyyy): 10-01-2025

☐ **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

Did you receive help from outside your patient group to complete your input?

☒ No

☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

Did you receive help from outside your patient group to collect or analyze any information used in your input?

☒ No

☐ Yes

If yes, please detail the help that was received and who provided it: Enter details about help received

C. New or Updated Conflict-of-Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 1: Conflict-of-Interest Declaration for Patient Group

	Approximate amount received			
Company	**≤ $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**> $50,000**
Enter company name	☐	☐	☐	☐
Abbvie	☐	☒	☒	☒
AstraZeneca	☐	☐	☒	☐
Apotex	☐	☐	☐	☒
Amgen	☐	☐	☐	☒
The Binding Site	☐	☐	☐	☒
BMS	☐	☐	☐	☒
FORUS Therapeutics	☐	☐	☐	☒
GSK	☐	☐	☐	☒
IMC	☐	☒	☐	☒
JAMP	☐	☐	☒	☐
Janssen	☐	☐	☐	☒
Merck	☐	☐	☒	☐
Pfizer	☐	☐	☐	☒
Rapid Novor	☐	☐	☐	☒
Roche	☐	☐	☒	☐
Sanofi	☐	☐	☐	☒
Sebia Diagnostics	☐	☐	☒	☐
Takeda	☐	☐	☒	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Appendix 2: Conflict-of-Interest Declarations for Clinician Groups

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  - include all new and updated declarations in a single document.

A. Assistance With Providing the Feedback

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Did you receive help from outside your clinician group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it: Enter details about help received

B. Conflict-of-Interest Declarations

List any companies or organizations that have provided your group or member(s) of your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review. **This is required for *each clinician* that contributed to the input — please add more tables as needed (copy and paste). It is preferred that all declarations be included in a single document.**

Declaration for Clinician 1

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ **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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 2: Conflict-of-Interest Declaration for Clinician 1

	Approximate amount received			
Company	**≤ $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**> $50,000**
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Input on Proposed Scope for Provisional Funding Algorithm

Patient, Clinician, or Industry Group Information

Project number: PH0068-000

Condition (or indication) under review: Multiple myeloma

Organization name: Ontario Health (Cancer Care Ontario) [OH-CCO] Hematology Cancer Drug Advisory Committee

Contact information (if comments require clarification)

Full name: Dr. Tom Kouroukis

Current position: Lead, OH-CCO Provincial Drug Reimbursement Program (PDRP) Hematology Cancer Drug Advisory Committee

Email: [redacted]

Phone: NA

Contact information will not be included in any public posting of this document.

For Both Rapid and Panel Provisional Funding Algorithms (Required)

Q1: Based on the proposed scope of the provisional funding algorithm, the other drugs that could be impacted, and the current reimbursement setting, what factors do you think should be considered in the development of the provisional funding algorithm? Please provide your input:

There is a fundamental difference in patients who have been BCMA exposed vs those who are BCMA refractory in terms of anticipated benefits of ciltacabtagene autoleucel (cilta-cel). We feel that BCMA exposed patients who have had a good response could benefit from cilta-cel as a later line of therapy. There are a number of patients in Canada who have been treated with belantamab mafodotin on study previously with great responses who should have cilta-cel as an option in their future.

For Panel Provisional Funding Algorithm Only (Not Required for Rapid Provisional Funding Algorithm)

Q2: Based on the implementation issues described in the proposed scope, what implementation issues could be addressed by the panel? Please provide your input:

How to prioritize patients who would benefit the most from cilta-cel in relation to other potential treatment options available?

How to decide which bispecific T-cell engagers to be used?

Q3: Are there any implementation issues that may not have been addressed in the proposed scope? Please provide your input:

NA

Appendix 1: Conflict-of-Interest Declarations for Patient Groups

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A. Patient Group Information

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

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B. Assistance With Providing Feedback

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☐ No
☐ Yes

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Enter details about help received

Did you receive help from outside your patient group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

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Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

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A. Assistance With Providing the Feedback

Did you receive help from outside your clinician group to complete your input?

☐ No
☒ Yes

If yes, please detail the help that was received and who provided it:

OH-CCO PDRP provided secretariat function to the group.

Did you receive help from outside your clinician group to collect or analyze any information used in your input?

☒ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

B. Conflict-of-Interest Declarations

List any companies or organizations that have provided your group or member(s) of your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review. This is required for each clinician that contributed to the input — please add more tables as needed (copy and paste). It is preferred that all declarations be included in a single document.

Declaration for Clinician 1

Full name: Dr. Tom Kouroukis

Current position: Lead, OH-CCO PDRP Hematology Cancer Drug Advisory Committee

Date form completed (dd-mm-yyyy): 09-01-2025

☒ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 2: Conflict-of-Interest Declaration for Clinician 1

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Declaration for Clinician 2

Full name: Dr. Christopher Cipkar

Current position: Member, OH-CCO PDRP Hematology Cancer Drug Advisory Committee

Date form completed (dd-mm-yyyy): 03-01-2025

☒ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 3: Conflict-of-Interest Declaration for Clinician 2

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 3

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 4: Conflict-of-Interest Declaration for Clinician 3

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 4

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 5: Conflict-of-Interest Declaration for Clinician 4

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 5

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 6: Conflict-of-Interest Declaration for Clinician 5

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Input on Proposed Scope for Provisional Funding Algorithm

Patient, Clinician, or Industry Group Information

Project number: PH0068-000

Condition (or indication) under review: Multiple Myeloma

Organization name: GlaxoSmithKline Inc.

Contact information (if comments require clarification)

Full name: [redacted]

Current position: Market Access Manager, Oncology

Email: [redacted]

Phone: [redacted]

Contact information will not be included in any public posting of this document.

For Both Rapid and Panel Provisional Funding Algorithms (Required)

Q1: Based on the proposed scope of the provisional funding algorithm, the other drugs that could be impacted, and the current reimbursement setting, what factors do you think should be considered in the development of the provisional funding algorithm? Please provide your input:

- Belantamab mafodotin is a first-in-class B-cell maturation antigen (BCMA) targeted antibody-drug conjugate (ADC) that can be partnered with other therapies with different mechanisms of action and has been shown to not interfere with the subsequent use of other anti-BCMA therapies.[1,2] Two belantamab combinations, belantamab, bortezomib, dexamethasone (BVd) and belantamab, pomalidomide, dexamethasone (BPd), are currently under review at CDA-AMC for the treatment of relapsed/refractory multiple myeloma (MM) and should be considered in scope during the development of the updated provisional funding algorithm (and be included should belantamab receive recommendations for reimbursement), similar to other indications where drugs under review have been considered in scope.[3] There is an unmet need for complementary BCMA-targeted treatments that can be used in a broader range of MM patients, that offer more ease of administration, less treatment burden, and that can preserve patient fitness so patients can proceed onto additional lines of treatment. The evidence submitted to CDA-AMC on belantamab comes from two head-to-head (triplet vs. triplet) phase 3 trials,[4,5] in contrast to

recently reimbursed bispecific anti-bodies (teclistamab and elranatamab), which were recommended for reimbursement (with conditions) based on single arm studies.[6,7]

- Published real world evidence (RWE) on treatment sequencing should be considered in addition to clinical trial data to inform the updated algorithm.
- GSK is pleased to provide the following list of published evidence related to treatment sequencing of belantamab and other BCMA-targeted therapies:
    - Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma. NEJM. 2024;391(5):393-407.
    - Dimopoulos MA, Beksac M, Pour L, et al. Belantamab mafodotin, pomalidomide, and dexamethasone in multiple myeloma. NEJM. 2024;391(5):408-421.
    - McCurdy A, Reece D, Louzada ML. et al. Belantamab mafodotin, pomalidomide, and dexamethasone for triple class exposed/refractory relapsed multiple myeloma: a subgroup analysis of the ALGONQUIN trial. Blood Cancer J. 2024;14 (1): 155.
    - Quach H. Reengaging life post-BCMA for myeloma. Blood 2024; 144 (23): 2365–2367.
    - Touzeau C, Krishnan AY, Moreau P, et al. Efficacy and safety of teclistamab in patients with relapsed/refractory multiple myeloma after BCMA-targeting therapies. Blood 2024; 144 (23): 2375–2388
    - Sharma R, Paul P, Masih-Khan E, et al. Outcomes of relapsed/refractory multiple myeloma patients receiving sequential therapies after exposure to T-cell redirected or BCMA-targeted novel immunotherapies. Blood 2024; 144 (Supplement 1): 1956.
    - Janakiram M, Tan CR, Popat R, et al. Real world evidence of outcomes of patients treated with talquetamab in a heavily pretreated population with multiple myeloma with high exposure to prior BCMA therapies- a report from the IMWG Consortium. Blood 2024; 144 (Supplement 1): 3368.
    - Dima D, Vazquez-Martinez MA, Davis JA et al. Outcomes of teclistamab (Tec) in patients with relapsed/refractory multiple myeloma (RRMM) with prior exposure to BCMA-directed therapy (BCMA-DT): a multicenter study from the U.S. Multiple Myeloma Immunotherapy Consortium. Blood 2024; 144 (Supplement 1): 897.
    - Snyder J, Ahmed N, Mahmoudjafari Z et al. Efficacy of BCMA T-Cell Engagers (TCE) Vs. Chimeric Antigen Receptor T-Cell Therapy (CAR-T) following BCMA-directed therapies, relapsed/refractory multiple myeloma: the chicken or the egg dilemma. Blood 2024; 144 (Supplement 1): 7098.

For Panel Provisional Funding Algorithm Only (Not Required for Rapid Provisional Funding Algorithm)

Q2: Based on the implementation issues described in the proposed scope, what implementation issues could be addressed by the panel? Please provide your input:

- The BCMA targeted drugs listed in the proposed scope, cilta-cel, teclistamab and elranatamab, were recently recommended (with conditions) for reimbursement for patients with relapsed/refractory MM. The CDA-AMC recommendations for these regimens[6-8] highlighted that their administration requires specialized treatment centres with infrastructure and resources; however, only a limited number of centres in Canada meet these requirements and have the expertise to deliver these treatments. For cilta-cel, the pCODR Expert Review Committee (pERC) called out the need for jurisdictions to implement fair and equitable priority-setting criteria for eligibility should the demand for cilta-cel exceed manufacturing or delivery capacity.[8] GSK is requesting that the evidence on sequencing, which may be limited, be considered with some allowance for uncertainty given these patient access issues and ensuing inequity, so that all patients can access a BCMA-targeted treatment at the appropriate time in their treatment journey.

Q3: Are there any implementation issues that may not have been addressed in the proposed scope? Please provide your input:

- The treatment landscape in MM has evolved from lines of therapy to classes of drug exposure. GSK suggests the next iteration of the provisional algorithm align with this evolution and be based on prior drug class exposure versus lines of therapy, as suggested in recent CDA-AMC reimbursement recommendations in MM.[6,7]
- A total of four drug submissions for MM are currently under review at CDA-AMC (the submissions for BVd and BPd, and two first-line quad regimens). To ensure timely drug access to patients, it's important that all these regimens be captured in the update of the provisional algorithm so that it is not considered out of date upon completion. Further, with the entry of quad regimens, funding rules on the use pomalidomide should also be reviewed.

References

1. Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma (Supplement). *NEJM*. 2024;391(5):393-407.
2. Lowther DE, Houseman EA, Han G, et al. No Evidence of BCMA expression loss or systemic immune impairment after treatment with the BCMA-targeted antibody-drug conjugate (ADC) belantamab mafodotin (Belamaf) in the DREAMM-1 and DREAMM-2 trials of patients with relapsed/refractory multiple myeloma (RRMM). *Blood.* 2022;140(Supplement 1):611-613.
3. CDA-AMC. Provisional Funding Algorithm: Proposed Scope for Endometrial Cancer. 2024. https://www.cda-amc.ca/sites/default/files/DRR/2024/PH0066_Endometrial_Cancer_proposed_scope.pdf. Accessed January 9, 2025.
4. Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma. *NEJM.* 2024;391(5):393-407.
5. Dimopoulos MA, Beksac M, Pour L, et al. Belantamab mafodotin, pomalidomide, and dexamethasone in multiple myeloma. *NEJM.* 2024;391(5):408-421
6. CADTH. CADTH Reimbursement Recommendation: Teclistamab (Tecvayli). *Canadian Journal of Health Technologies.*2024;4(4):1-37. https://www.cda-amc.ca/sites/default/files/DRR/2024/PC0332%20Tecvayli%20-%20Final_Rec.pdf. Accessed January 9, 2025.
7. CADTH. CADTH Reimbursement Recommendation: Elranatamab (Elrexfio). *Canadian Journal of Health Technologies.* 2024;4(6):1-33. https://www.cda-amc.ca/sites/default/files/DRR/2024/PC0315_Final_Recommendation.pdf. Accessed January 9, 2025.
8. CDA-AMC. Reimbursement Recommendation: Ciltacabtagene Autoleucel (Carvykti). 2024;4(11):1-33. https://www.cda-amc.ca/sites/default/files/DRR/2024/PG0361REC_Carvykti_Final.pdf. Accessed January 9, 2025.

Appendix 1: Conflict-of-Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the 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 input from patient groups.
- We may contact your group with further questions, as needed.

A. Patient Group Information

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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

Did you receive help from outside your patient group to complete your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

Did you receive help from outside your patient group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

C. New or Updated Conflict-of-Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 1: Conflict-of-Interest Declaration for Patient Group

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Appendix 2: Conflict-of-Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the 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 clinician groups.
- We may contact your group with further questions, as needed.
- For conflict-of-interest declarations:
  - list any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review
  - provide declarations for each clinician that contributed to the input
  - include only new conflict-of-interest declarations or ones that require updating if your clinician group provided input at the beginning of the outset of the review; for all others, please list the clinicians whose provided input is unchanged
  - add more tables as needed (copy and paste)
  - include all new and updated declarations in a single document.

A. Assistance With Providing the Feedback

Did you receive help from outside your clinician group to complete your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

Did you receive help from outside your clinician group to collect or analyze any information used in your input?

☐ No
☐ Yes

If yes, please detail the help that was received and who provided it:

Enter details about help received

B. Conflict-of-Interest Declarations

List any companies or organizations that have provided your group or member(s) of your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review. This is required for each clinician that contributed to the input — please add more tables as needed (copy and paste). It is preferred that all declarations be included in a single document.

Declaration for Clinician 1

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 2: Conflict-of-Interest Declaration for Clinician 1

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Declaration for Clinician 2

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 3: Conflict-of-Interest Declaration for Clinician 2

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 3

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 4: Conflict-of-Interest Declaration for Clinician 3

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 4

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 5: Conflict-of-Interest Declaration for Clinician 4

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.

Declaration for Clinician 5

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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.

List any companies or organizations that have provided you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 6: Conflict-of-Interest Declaration for Clinician 5

Company	Approximate amount received			
	≤ $5,000	$5,001 to $10,000	$10,001 to $50,000	> $50,000
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐
Enter company name	☐	☐	☐	☐

Note: To add more rows, place cursor in bottom row and select the plus (+) sign on right side of row.