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CADTH

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CADTH Reimbursement Recommendation

# Idecabtagene Vicleucel (Abecma)

**Indication:** For the treatment of adult patients with multiple myeloma who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and who are refractory to their last treatment.

**Sponsor:** Celgene Inc., a Bristol Myers Squibb Company

**Final recommendation:** Do not reimburse

CADTH

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**Redactions:** Confidential information in this document has been redacted at the request of the sponsor in accordance with the *CADTH Drug Reimbursement Review Confidentiality Guidelines.*

**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

**Funding:** CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

# Summary

CADTH

## What Is the CADTH Reimbursement Recommendation for Abecma?

CADTH recommends that Abecma should not be reimbursed by public drug plans for the treatment of multiple myeloma.

### Why Did CADTH Make This Recommendation?

Evidence from a clinical trial suggested that Abecma is associated with an improvement in response rate in patients with heavily treated multiple myeloma. No conclusions could be drawn for other important outcomes, including duration of response, overall survival, progression-free survival, and quality of life.

Patients identified a need for treatments that can prolong remission and improve quality of life and symptoms, and that have fewer side effects. It is not clear whether Abecma meets these needs.

## Additional Information

### What Is Multiple Myeloma?

Multiple myeloma is a cancer of plasma cells (the white blood cells that make immunoglobulins) that is more common in older adults and accounts for 10% to 15% of all blood cancers. Many patients can fail to respond to initial treatments and relapse, and frequently undergo multiple treatment regimens.

### Unmet Needs in Multiple Myeloma

In heavily treated multiple myeloma patients whose life expectancy is limited, only a few treatment options are available. Therapies extending survival and quality of life are needed.

### How Much Does Abecma Cost?

Treatment with Abecma is expected to cost approximately $545,000 per patient per treatment course.

## Recommendation

The CADTH pCODR Expert Review Committee (pERC) recommends that idecabtagene vicleucel should not be reimbursed for the treatment of adult patients with multiple myeloma who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and who are refractory to their last treatment.

## Rationale for the Recommendation

pERC reviewed 1 phase II, open-label, single-arm study (KarMMa, N = 140) of idecabtagene vicleucel in patients with relapsed or refractory multiple myeloma (RRMM). At a median follow-up time of 11.3 months, the overall response rate (ORR) was 81.5% (95% CI, 68.6% to 90.7%) and the complete response (CR) rate was 35.2% (95% CI, 22.7% to 49.4%) in patients who received the target dose of $450 \times 10^6$ chimeric antigen receptor (CAR) T cells. Although results of the KarMMa study appear to suggest that treatment with idecabtagene vicleucel is associated with an improvement in ORR and CR rate in patients with RRMM, the study was associated with major limitations, specifically the single-arm design and lack of a control group. These limitations contribute to the lack of confidence in the observed benefits relative to other therapies and lead to considerable uncertainty in the results. Duration of response (DOR), time to progression, overall survival, and progression-free survival were evaluated as secondary outcomes in the KarMMa study, but none of these outcomes were controlled for multiplicity. Results of health-related quality of life outcomes were reported descriptively and could not be interpreted due to missing data. Based on input received by CADTH, patients expressed the need for effective treatments that offer prolonged remission and better control of symptoms with fewer side effects and better quality of life. Idecabtagene vicleucel offers a subsequent therapy for a heavily pretreated population in the form of a single treatment. pERC recognized the unmet medical need in RRMM patients who are triple-class exposed; however, pERC was unable to determine whether treatment with idecabtagene vicleucel would meet patients' needs due to limitations of the trial design and with the statistical analyses. Limited evidence was available regarding the long-term treatment effects of idecabtagene vicleucel; therefore, whether responses observed in the KarMMa study would be maintained beyond 16 months (at the trial data cut-off corresponding to a median follow-up of 11.3 months) was also uncertain.

Indirect evidence comparing the results from KarMMa to real-world evidence suggested that treatment with idecabtagene vicleucel may be associated with improvements in survival outcomes, ORR, and DOR. However, these results must be considered within the context of methodological limitations such as risk of bias due to inherent design differences in the evidence used in these comparisons that cannot be adjusted for statistically, the potential impact of unmeasured and unaccounted prognostic factors and effect modifiers in the models, and undermined generalizability by the inclusion of irrelevant comparators.

The submitted price of idecabtagene vicleucel is $545,000 per infusion (target dose = $450 \times 10^6$ CAR T cells; range = $275 \times 10^6$ to $520 \times 10^6$). CADTH was unable to estimate the cost-effectiveness of idecabtagene vicleucel due to the lack of comparative clinical information and the extent of clinical benefit predicted beyond the trial observation period (i.e., more

than 94% of the quality-adjusted life-years associated with idecabtagene vicleucel occurring beyond 1 year).

## Discussion Points

- The CADTH pCODR Expert Review Committee (pERC) discussed that idecabtagene vicleucel is a complex therapy involving high resource utilization. Lymphodepleting chemotherapy (LDC) consisting of cyclophosphamide and fludarabine is required before treatment with idecabtagene vicleucel. Bridging therapy may also be administered for disease control, at the discretion of the physician, after leukapheresis is completed and before the initiation of LDC.
- Given the lack of long-term evidence and the single-arm study design of the pivotal trial, there is substantial uncertainty associated with the clinical and economic evidence. pERC noted that the study population for the KarMMa trial consisted of predominately late-stage patients with a median of 6 years since diagnosis who had been heavily treated with a median of 6 prior antimyeloma regimens. Therefore, the results of this single-arm trial might not be readily generalizable to all patients with RRMM who are triple-class exposed.
- pERC noted that treatment with idecabtagene vicleucel was associated with frequent adverse effects, as observed in the KarMMa study. Adverse events (AEs) associated with a risk of notable toxicity included febrile neutropenia, neurotoxicity (including confusional state and encephalopathy), and cytokine release syndrome.
- pERC agreed with the clinical expert consulted by CADTH that there is an unmet need due to very limited options for patients with RRMM after third and fourth lines of therapy, and acknowledged that idecabtagene vicleucel represents a subsequent, single therapy for a heavily pre-treated population.
- pERC noted that this complex therapy may pose significant hardship and financial burden, and inequitable access to patients and caregivers who have to travel to distant centres.
- pERC discussed ethical concerns driven by the high cost of idecabtagene vicleucel, limited number of centres that are authorized to administer the therapy, and geographic constraints on access. As part of its consideration of the feasibility of adoption, pERC also discussed barriers to implementation of idecabtagene vicleucel. pERC noted that CAR T-cell therapies are complex, require highly specialized centres with expertise in cellular therapies for administration, and may not be readily accessible for all patients in Canada. It was noted that patients from remote areas would need to have a prolonged stay at or near specialized centres and that relocation and interprovincial travel would be required for some patients to access this therapy. Travel costs for patients and their caregivers and the time spent away from work may disproportionately affect certain populations. Furthermore, pERC agreed with clinical experts that some provinces would not have the capacity to assess patients' eligibility for treatment with idecabtagene vicleucel, which would result in substantive out-of-pocket costs for those patients who have to travel out of province to meet the eligibility requirements.
- pERC discussed that comparative data from head-to-head studies are needed to help address some of the uncertainties identified in the current review. pERC acknowledged that the KarMMa-3 trial, an ongoing phase III randomized controlled trial comparing idecabtagene vicleucel with standard treatment regimens for RRMM, is expected to provide additional data to address the place of idecabtagene vicleucel in the treatment of RRMM.

## Background

Idecabtagene vicleucel has a Health Canada indication for the treatment of adult patients with multiple myeloma who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and who are refractory to their last treatment. Idecabtagene vicleucel is a cell therapy formed by chimeric antigen receptor (CAR)-positive T cells directed against the B-cell maturation antigen. It is available as a cell suspension in 1 or more patient-specific infusion bags, and the Health Canada–approved target dose is $450 \times 10^6$ CAR T cells (within a range of $275 \times 10^6$ to $520 \times 10^6$ CAR T cells) for IV infusion.

## Sources of Information Used by the Committee

To make their recommendation, the Committee considered the following information:

- a review of 1 single-arm, phase II clinical study (KarMMa) in patients with multiple myeloma who have been treated with at least 3 previous regimens, and a review of 2 indirect comparisons
- patients' perspectives gathered from 1 patient group: Myeloma Canada
- three clinical specialists with expertise diagnosing and treating patients with multiple myeloma
- input from 2 clinician groups: the Canadian Myeloma Research Group and the Ontario Health group (previously Cancer Care Ontario)
- a review of the pharmacoeconomic model and report submitted by the sponsor
- a review of relevant ethical issues related to idecabtagene vicleucel from the published literature.

## Patient Input

One patient group (Myeloma Canada) provided input for this submission. Patient perspectives were obtained from a patient survey accessed through email and social media from December 17, 2020, to January 4, 2021. A total of 388 individuals with myeloma responded to the survey. The following is a summary of key input from the perspective of the patient group.

- Overall, patients described the negative impact of myeloma on daily life, including their ability to work, travel, and exercise. Patients who have been heavily treated expect new treatment options to provide prolonged remission, better quality of life and overall health, better control of myeloma symptoms, and fewer side effects.
- Myeloma Canada surveyed patients' understanding of CAR T-cell therapy and concluded that more than half of participants understand the process involved. More than half felt that CAR T-cell immunotherapy could improve their long-term health outlook, although they had concerns about the possibility of requiring bridging therapy and about potential side effects.

- The patient group highlighted that many Canadians are looking for new options for effective treatments, especially when they reach the point of multiple therapies and have experienced relapses or become refractory with the available regimens. Myeloma Canada stated that CAR T-cell therapy represents an important benefit to these patients, despite the number and severity of the side effects.

## Drug Plan Input

The drug programs raised questions concerning how to identify patients for whom treatment with idecabtagene vicleucel would be most appropriate and noted that the choice of comparator in the submitted trial would need special consideration because there is no clear standard of care (i.e., when reaching fourth line of therapy). They also noted that access to treatment with idecabtagene vicleucel may be limited due to jurisdictional capacity and that out-of-province care may be needed for proper administration. The Provincial Advisory Group (PAG) raised concerns that idecabtagene vicleucel is a resource-intensive therapy given the need for leukapheresis, cell processing, LDC, potential use of bridging therapy, and management of adverse effects.

## Clinical Evidence

### Clinical Trials

The systematic review included 1 single-arm, phase II clinical study (KarMMa) in patients with multiple myeloma who had been treated with at least 3 previous regimens, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and who were refractory to their last treatment. The main objective of the study was to evaluate the efficacy and harms of idecabtagene vicleucel. Enrolled patients (N = 140) underwent leukapheresis (i.e., drug manufacturing) and, if necessary, a bridging therapy (with corticosteroids, alkylating agents, immunomodulatory agents, proteasome inhibitors, and/or anti-CD38 antibodies alone or in combination) while the idecabtagene vicleucel was manufactured. All patients were required to undergo LDC with cyclophosphamide and fludarabine 5 days before the idecabtagene vicleucel infusion. Of the 140 patients from the enrolled population, 128 received the idecabtagene vicleucel infusion and were included as the idecabtagene vicleucel–treated population for the primary analysis of efficacy and safety. Patients received target doses of $150 \times 10^6$, $300 \times 10^6$, or $450 \times 10^6$ CAR T cells. They were followed for at least 24 months and then asked to participate in a separate long-term follow-up study. The median age of the 140 enrolled patients was 60.5 years (range = 33 to 78), 82 (58.6%) were male, the median time since diagnosis was 6 years (range = 1 to 18 years), 46 (32.9%) had a high cytogenetic risk, and 131 (93.6%) had received a stem cell transplant.

The main limitation of the KarMMa trial is the lack of a comparator arm. The only outcomes adjusted for multiplicity were overall response rate (ORR) and complete response (CR) rate. Effect estimates on health-related quality of life (HRQoL) were uncertain due to increasing missing data at later time points of measurement.

## Outcomes

Outcomes were defined a priori in the CADTH systematic review protocol. The Committee discussed the following: ORR as the primary outcome, CR as a key secondary outcome, and other secondary outcomes included the duration of response (DOR), time to response (TTR), time to progression (TTP), minimal residual disease (MRD) negative status, overall survival (OS), progression-free survival (PFS), and HRQoL measured with the European Organization for Research and Treatment of Cancer – Quality of Life C30 (EORTC QLQ-C30) Questionnaire, the European Organization for Research and Treatment of Cancer – Quality of Life Multiple Myeloma (EORTC QLQ-MY20) Module, and the EuroQoL 5 dimension 5-scale (EQ-5D-5L) questionnaire.

## Efficacy

At a median follow-up time of 11.3 months, the ORR in the total idecabtagene vicleucel–treated population was 73.4% (95% CI, 65.8 to 81.1; P < 0.0001) and 81.5% (95% CI, 68.6 to 90.7) in the target dose of 450 × $10^6$ CAR T-cells group. Given that the test for ORR (primary end point) was positive, the key secondary efficacy end point of CR rate was tested. In the total idecabtagene vicleucel–treated group, 40 of 128 patients achieved a CR (CR = 31.3%; 95% CI, 23.2% to 39.3%; P < 0.0001); the CR rate was 35.2% (95% CI, 22.7% to 49.4%) in the target dose of 450 × $10^6$ CAR T-cells group.

The DOR, TTR, and TTP were evaluated in the KarMMa trial as secondary end points. For the population with a target dose of 450 × $10^6$ CAR T cells, the median DOR was 11.30 months (95% CI, 9.17 to 11.43) and the median TTR was 1.0 month (range = 0.9 to 2.0). TTP was not assessed in the group with a target dose of 450 × $10^6$ CAR T cells. Further, an MRD negative status with a complete response or better was observed in 13 of 54 (24.1%) patients in the target dose of 450 × $10^6$ CAR T cells group.

In the all-treated population, the observed median OS rate was 18.2 months (95% CI, 18.0 to not estimable), with 77% of individuals alive at 12 months. The OS rate was not estimable in patients in the target dose of 450 × $10^6$ CAR T-cells group. Similarly, based on the Kaplan-Meier estimates, the median PFS rate was 8.6 months (95% CI, 5.6 to 11.3) in the idecabtagene vicleucel–treated group with 34% of patients event-free at 12 months and 11.3 months (95% CI, 8.8 to 12.4) in the target dose of 450 × $10^6$ CAR T-cells group, which indicates a meaningful benefit for patients treated with idecabtagene vicleucel.

For HRQoL outcomes, results of the KarMMa trial suggest that idecabtagene vicleucel treatment may be associated with improvements in the Fatigue, Pain, Physical Functioning, and Global Health/QoL subscales of the EORTC QLQ-C30 by reaching points of meaningful clinical significance above the thresholds of probably benefit according to minimally important differences established in the literature. On average, no clinically meaningful deterioration in the EORTC QLQ-C30 Cognitive Functioning and EORTC QLQ-MY20 Disease Symptoms and Side Effects subscales were observed post-treatment. No changes from baseline were observed in any of the EQ-5D-5L subscales of this measurement.

## Harms (Safety)

Adverse events were reported in all 128 (100%) patients treated with idecabtagene vicleucel. Most AEs, with the exception of hypogammaglobulinemia and infections, occurred within the first 8 weeks after infusion. The most commonly reported AEs were hematologic toxic effects, including neutropenia in 117 patients (91.4%), cytokine release syndrome (CRS) in

107 patients (83.6%), anemia in 89 patients (69.5%), and thrombocytopenia in 81 patients (63.3%). A total of 86 (67.2%) patients had at least 1 serious AE. The most frequently reported serious AEs (≥ 5% of patients) were CRS in 22 patients (17.2%), general physical health deterioration in 13 (10.2%) patients, pneumonia in 11 (8.6%) patients, and febrile neutropenia in 9 (7.0%) patients.

In total, 8 patients died after leukapheresis and before receiving idecabtagene vicleucel infusion: 5 patients (3.6%) died after leukapheresis and before starting LDC, and 3 patients (2.1%) died after starting LDC and before receiving the idecabtagene vicleucel infusion. As of the data cut-off date, 34 patients (26.6%) in the idecabtagene vicleucel–treated population died on or after the idecabtagene vicleucel infusion; 24 of these deaths were attributed to the malignant disease under study or a complication due to the malignant disease under study. Notable harms were identified according to the protocol for this review. Febrile neutropenia was present in 21 patients (16.4%) of the idecabtagene vicleucel–treated population. A total of 23 patients (18.0%) in the idecabtagene vicleucel–treated population had investigator-identified neurotoxicity on or after the idecabtagene vicleucel infusion. CRS on or after the idecabtagene vicleucel infusion was present in 107 patients (83.6%).

## Indirect Evidence

Two sponsor-submitted analyses compared the information from the single-arm KarMMa study to observational evidence obtained from individual patient data or aggregated published data. The first analysis (NDS-MM-003 or KarMMa-RW) was a comparison of the 128 idecabtagene vicleucel–treated patients from the original KarMMa trial with 190 patients with similar eligibility criteria obtained from a set of "real-world" patient-level data collected from various sources, including databases and clinical sites. To decrease the imbalances or differences in patients from the real-world evidence (RWE) when compared to the KarMMa population, propensity scores were created and used in an inverse probability treatment weighting.

The second analysis was a matching adjusted indirect comparison (MAIC) that compared the idecabtagene vicleucel–treated population from the KarMMa trial to aggregated data from a published RWE study (MAMMOTH). This analysis aimed to provide a comparator arm, with adjustment for differences in baseline characteristics, prognostic factors, and effect modifiers, and obtained an adjusted effect estimate for decision-makers and stakeholders given the lack of a direct, head-to-head comparison of idecabtagene vicleucel to relevant comparators.

From the NDS-MM-003 analysis, the ORR was lower in the eligible RRMM cohort compared with the idecabtagene vicleucel cohort (32.2% versus 76.4%; relative risk [RR] = 2.4; 95% CI, 1.7 to 3.3; P < 0.0001). A comparison between the 2 groups yielded an OS hazard ratio (HR) of 0.42 (95% CI, 0.26 to 0.68) that favoured the idecabtagene vicleucel cohort compared with the eligible RRMM cohort treated with available therapy (P = 0.0005). The median TTR for responders was 1.1 months (range = 0.2 to 8.6) in the eligible RRMM cohort versus 1.0 month (range = 0.5 to 8.8) in the idecabtagene vicleucel cohort. Similarly, the HR for DOR was 0.55 (95% CI, 0.29 to 1.06; P = 0.0725) and the HR for PFS was 0.47 (95% CI, 0.33 to 0.67; P < 0.0001).

The second analysis using MAIC and comparing with the MAMMOTH study yielded similar results. Idecabtagene vicleucel in the treated population was more efficacious than conventional care in terms of ORR, ([redacted]) and also in the population

using the target dose of 450 × $10^6$ CAR T cells. The PFS rate was better for the idecabtagene vicleucel–treated population ([redacted]) and for patients who received the target dose of 450 × $10^6$ CAR T cells ([redacted]). OS was also better; the OS rate for the idecabtagene vicleucel–treated population was higher than that of conventional care in the treated population from the MAMMOTH study, in the adjusted MAIC ([redacted]) and target dose ([redacted]).

Both comparisons present important limitations, such as risk of bias due to inherent design differences in the bodies of evidence, the potential impact of unmeasured and unaccounted prognostic factors and effect modifiers in the models, and undermined generalizability by the inclusion of irrelevant comparators. Given the limitations of the 2 indirect treatment comparisons and the absence of direct comparative evidence, any potential benefit of idecabtagene vicleucel over other treatment regimens used in this patient population remains unknown.

# Economic Evidence

## Cost and Cost-Effectiveness

The submitted price of idecabtagene vicleucel is $545,000 per infusion (target dose of 450 × $10^6$ CAR-positive T cells, within a range of 275 × $10^6$ to 520 × $10^6$ CAR-positive T cells), excluding the costs associated with leukapheresis, bridging therapies, and LDC.

The sponsor submitted a cost-utility analysis based on a 3-state partitioned survival model that compared idecabtagene vicleucel to conventional care (defined as a basket of chemotherapy regimens) for the treatment of adult patients with RRMM who have received at least 3 prior regimens, including regimens with an immunomodulatory drug, a proteasome inhibitor, and an anti-CD38 antibody. The analysis was conducted from the perspective of a Canadian publicly funded health care system adopting a lifetime time horizon (i.e.,15 years). The proportion of patients who were progression-free, experienced progressive disease, or were dead at any time over the model time horizon was derived from non–mutually exclusive survival curves. The clinical efficacy of idecabtagene vicleucel was informed by patients who received the target dose within the KarMMa trial. To estimate the comparative treatment effects to conventional care, 190 patients within the retrospective NDS-MM-003 database were selected for meeting the key eligibility criteria of the KarMMa trial based on select baseline characteristics and trimmed stabilized inverse probability of treatment weighting was applied to patients from the treated population from the NDS-MM-003 and the KarMMa studies (i.e., those who received idecabtagene infusion). Treatment and health-state utilities were sourced from the KarMMa trial and from published studies.

CADTH identified several key limitations with the submitted analysis:

- The clinical efficacy of idecabtagene vicleucel is uncertain. KarMMa is an open-label, single-arm, phase II study and the efficacy of idecabtagene vicleucel is further expected to be dependent on several implementation factors.
- Relative effectiveness estimates (i.e., PFS and OS) of idecabtagene vicleucel versus conventional care were obtained by comparing the treated population in the KarMMa trial to a retrospective database of patients using different MM treatments. Despite

adjustments for several known prognostic variables using propensity scores, there remains significant uncertainty about the relative efficacy of idecabtagene vicleucel compared with conventional care.

- Clinical experts noted that the sponsor's chosen OS and PFS curves were optimistic compared with real-world clinical experience and, given that the OS data were immature at the trial data cut-off, the true long-term effectiveness (and relative effectiveness) remains unknown.
- The comparator was a pooled strategy of different oncology regimens that does not reflect Canadian practice. Furthermore, there were inconsistencies between the regimens informing costs for conventional care and those informing clinical efficacy inputs.
- Treatment-specific utility weights were applied that lacked face validity and, in some instances, double-counted the disutility associated with AEs and treatment administration in favour of idecabtagene vicleucel.

The issues with the clinical data prohibit a reasonable assessment of cost-effectiveness because there is no clear resolution to address the clinical uncertainties. As such, a CADTH base case could not be derived. CADTH undertook a series of exploratory reanalyses, focused on the treated population, which indicated that the incremental cost-effectiveness ratio (ICER) of idecabtagene vicleucel was likely to be higher than that estimated by the sponsor. The ICERs were very sensitive to different assumptions regarding relative efficacy and the cost of idecabtagene vicleucel. One set of exploratory reanalyses attempted to address some of the identified limitations including adjusting the distribution of regimens informing the cost of conventional care and removing treatment-specific utilities. A different combination of possible efficacy scenarios was tested on top of the changes noted previously, and the deterministic ICER for idecabtagene vicleucel was found to range from $286,142 to $1,276,217 per quality-adjusted life-year (QALY) compared with conventional care. Price reductions of at least 83% to 94% would be required to achieve an ICER of $50,000 per QALY.

### Budget Impact

The sponsor estimated the incremental budget impact of reimbursing idecabtagene vicleucel to be $200.2 million over 3 years, based on a health care system perspective. CADTH identified limitations with the submitted budget impact analysis and undertook reanalyses which estimated the incremental budget impact of reimbursing idecabtagene vicleucel to be $328.4 million over 3 years. The results were primarily driven by the price of idecabtagene vicleucel and the number of patients receiving idecabtagene vicleucel.

## Ethical Considerations

The empirical and normative literature related to the use of idecabtagene vicleucel and experiences of adult patients with multiple myeloma were reviewed for ethical content, using methods of qualitative description to highlight ethical considerations and themes. A total of 61 publications met the inclusion criteria and were included in the report. None directly reported on the use of idecabtagene vicleucel for multiple myeloma; instead, multiple myeloma incidence, treatment, access, costs of therapies, clinical trial inclusion, and clinical decision-making were explored.

Findings indicate that there are disparities in the incidence, treatment, and outcomes of multiple myeloma along racial, socioeconomic, age, and geographical lines. Similarly, there are disparities in access to and receipt of treatment of multiple myeloma; older adults and racialized communities or ethnic minorities, or those of lower socioeconomic status, are less likely to receive treatment. These considerations are amplified when demand for CAR T-cell therapies outstrips supply and resources. An analysis of large American clinical trials revealed that there are also disparities in inclusion in clinical trials for multiple myeloma therapies. Racial and ethnic minorities tend to be under-represented, which in turn may lead to limited understanding and elimination of the disparities identified. Racial minority groups may have limited access to insurance (this may not be representative of access in Canada) and academic trial centres, and may have multiple comorbidities that render them ineligible to participate in trials.

Patients eligible for CAR T-cell therapies often have few therapeutic options and thus may be willing to pursue high-risk treatments, highlighting a need to consider and identify the appropriate balance of risks and benefits for patients receiving these therapies.

# CADTH pan-Canadian Oncology Drug Review Expert Review Committee (pERC) Information

## Initial meeting: May 14, 2021

### Members of the Committee

Dr. Maureen Trudeau (Chair), Dr. Catherine Moltzan (Vice-Chair), Mr. Daryl Bell, Dr. Jennifer Bell, Dr. Kelvin Chan, Dr. Matthew Cheung, Dr. Winson Cheung, Dr. Michael Crump, Dr. Avram Denburg, Dr. Leela John, Dr. Christine Kennedy, Dr. Christian Kollmannsberger, Mr. Cameron Lane, Dr. Christopher Longo, Ms. Valerie McDonald, Dr. Marianne Taylor, and Dr. W. Dominika Wranik.

**Regrets**: One expert committee member did not attend.

**Conflicts of interest**: None

## Reconsideration meeting: October 13, 2021

### Members of the Committee

Dr. Maureen Trudeau (Chair), Dr. Catherine Moltzan, Mr. Daryl Bell, Dr. Jennifer Bell, Dr. Matthew Cheung; Dr. Winson Cheung, Dr. Michael Crump, Dr. Leela John, Dr. Christian Kollmannsberger, Mr. Cameron Lane, Dr. Christopher Longo, Ms. Amy Peasgood, Dr. Anca Prica, Dr. Adam Raymakers, Dr. Patricia Tang, Dr. Marianne Taylor, and Dr. W. Dominika Wranik.

**Regrets**: Two expert committee members did not attend.

**Conflicts of interest**: None