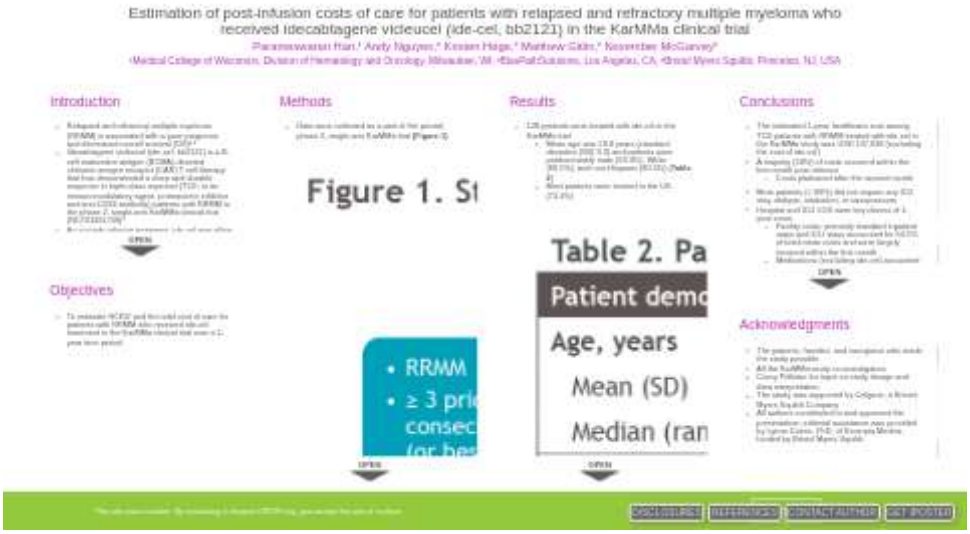
Estimation of post-infusion costs of care for patients with relapsed and refractory multiple myeloma who received idecabtagene vicleucel (ide-cel, bb2121) in the KarMMa clinical trial



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INTRODUCTION

- Relapsed and refractory multiple myeloma (RRMM) is associated with a poor prognosis and decreased overall survival (OS)[1,2]
- Idecabtagene vicleucel (ide-cel, bb2121) is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell therapy that has demonstrated a deep and durable response in triple-class exposed (TCE; to an immunomodulatory agent, proteasome inhibitor and anti-CD38 antibody) patients with RRMM in the phase 2, single-arm KarMMa clinical trial (NCT03361748)[3]
- As a single-infusion treatment, ide-cel may allow patients to experience longer treatment-free periods, which may result in reduced healthcare resource utilization (HCRU) and total costs of care

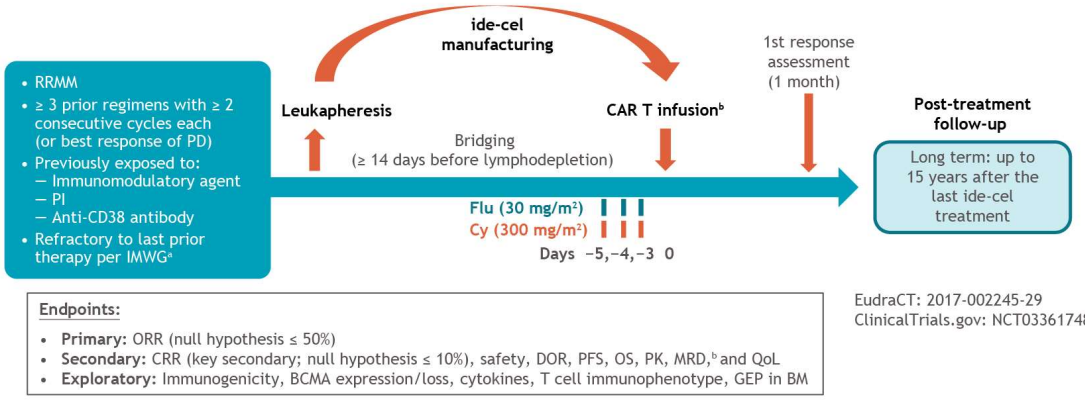
OBJECTIVES

- To estimate HCRU and the total cost of care for patients with RRMM who received ide-cel treatment in the KarMMa clinical trial over a 1-year time period

METHODS

- Data were collected as a part of the pivotal, phase 2, single-arm KarMMa trial **(Figure 1)**

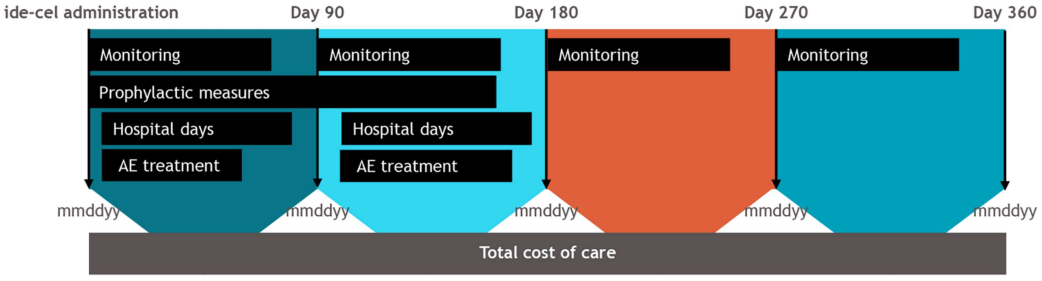
Figure 1. Study design of the KarMMa clinical trial



Data cutoff: January 14, 2020 (N = 128).
[a]Defined as documented disease progression during or within 60 days from last dose of prior antimyeloma regimen; [b]By next-generation sequencing.
BCMA, B cell maturation antigen; BM, bone marrow; CAR, chimeric antigen receptor; CRR, complete response rate; Cy, cyclophosphamide; DOR, duration of response; Flu, fludarabine; GEP, gene expression profile; IMWG, International Myeloma Working Group; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; QoL, quality of life; RRMM, relapsed and refractory multiple myeloma.

- This study was a retrospective analysis of the analytic data model (ADaM) databases from the KarMMa clinical trial 12 + 1 month data cut
  - 2-step methodology (**Figure 2**)
    1. Identify key HCRU from ide-cel treatment using the KarMMa clinical trial databases using a 1-year time horizon
    2. Apply unit costs to each HCRU and aggregate across 1 year to estimate total cost of care
- Key HCRU inputs and costs are shown in **Table 1**

Figure 2. Method to identify total cost of care



Unit costs for all HCRU are assumed to represent the cost to the health system (all providers) and were obtained from public sources and peer-reviewed literature.
All costs were presented in 2020 US dollars.
AE, adverse event; HCRU, healthcare resource utilization.

Table 1. Key HCRU inputs and costs

Category	Healthcare resource	Cost value, USD	Data source
Facility	Inpatient stay	2,542 per day	Health Care Utilization Project - National Inpatient Sample 2016[a]
	ICU stay	7,556 per day	Dasta et al, 2005[d]
Diagnostics	Diagnostics labs[b]	6-17 per test	Medicare Clinical Laboratory Fee Schedule 2020
	Diagnostic tests[c]	17-865	Medicare Physician Fee Schedule/ Outpatient Prospective Payment System 2020
Medications[d]	Oncology supportive care (granulocyte colony-stimulating factors, transfusions, anti-anemia drugs, anti-emetics)	< 1-8,572	IBM Truven Micromedex® RED BOOK - Wholesale Acquisition Costs, 2020
	Prophylactic treatments (antibiotics, proton pump inhibitors, H2 blockers, seizure prophylaxis, intravenous immunoglobulin)		
	Other AE management (anti-pyretics/ analgesics, tocilizumab and other anti-cytokine agents, corticosteroids, vasopressors)		
	Transfusions	36-140	Medicare Physician Fee Schedule/ Outpatient Prospective Payment System 2020
	Supplemental oxygen	76 per month	Medicare Durable Medicare Equipment Fee Schedule 2020
Procedures	Dialysis	640 per day	Medicare Outpatient Prospective Payment System 2020
	Mechanical ventilation[e]	2,783 per day	Dasta et al, 2005[d]

[a]Inflated to 2020 US dollars; [b]Diagnostic labs included comprehensive metabolic panel, C-reactive protein, ferritin, complete blood count, coagulation panel, cytokine panel, immunoglobulin, and cerebrospinal fluids; [c]Diagnostic tests included CT scan with contrast, MRI scan with contrast, PET scan with contrast, EEG, ECG/EKG, and tumor biopsy; technical component and physician's component costs were included; [d]Cost of ide-cel was not included in this analysis; [e]Intubation was used as a proxy to indicate mechanical ventilation.
AE, adverse event; CT, computed tomography; ECG/EKG, electrocardiography; EEG, electroencephalography; HCRU, healthcare resource utilization; ICU, intensive care unit; MRI, magnetic resonance imaging; PET, positron emission tomography; USD, US dollars.

Cost calculations

- Due to right censoring (loss to follow-up, patient death, discontinuation, or data cutoff date), a by-month cost calculation methodology was adopted
  - Costs and HCRU were partitioned by month following ide-cel administration
  - Costs within each month were evaluated for each partition
  - The mean was calculated among patients with available data on or after the partitioned month
  - Costs were aggregated across months (partitions) to estimate a mean total cost (**Figure 3**)

Figure 3. Total cost calculation

$$\text{Total Cost} = \text{AvgCost}_{\text{Month 1(n=128)}} + \text{AvgCost}_{\text{Month 2(n=127)}} + \text{AvgCost}_{\text{Month 3(n=122)}} + \ldots + \text{AvgCost}_{\text{Month 12(n=94)}}$$

AvgCost refers to the mean cost for the specified month.

RESULTS

- 128 patients were treated with ide-cel in the KarMMa trial
  - Mean age was 59.8 years (standard deviation [SD] 9.3) and patients were predominately male (59.4%), White (80.5%), and non-Hispanic (80.5%) (**Table 2**)
  - Most patients were treated in the US (73.4%)

Table 2. Patient demographics and characteristics

Patient demographics and characteristics	Patients (N = 128)
Age, years	
Mean (SD)	59.8 (9.3)
Median (range)	60.5 (33.0-78.0)
Male, n (%)	76 (59.4)
Race, n (%)	
White	103 (80.5)
Black or African American	6 (4.7)
Other	19 (14.8)
Ethnicity, n (%)	
Not Hispanic or Latino	103 (80.5)
Prior anti-multiple myeloma regimens	
Mean (SD)	6.52 (3.0)
Median (range)	6.0 (3-16)
Tumor burden, n (%)	
High	65 (50.8)

SD, standard deviation.

- Few patients required dialysis (n = 1; 0.8%) or intubation (n = 5; 3.9%) and a minority (n = 25; 19.5%) had an intensive care unit (ICU) stay (**Table 3**)
- Among all patients, mean (SD) hospital length of stay (LOS) was 21.4 (12.0) days for inpatient stays and 1.3 (3.4) days for ICU stays (**Table 4**)
  - Total LOS ranged from 15 to 114 days, with a mean (SD) of 22.7 (12.5) days
- Estimated mean 1-year post-infusion total cost of care was USD 107,699 (**Figure 4**)
- Most (58.0%) 1-year costs were incurred in the first month following infusion and were primarily driven by facility costs, namely standard inpatient and ICU stays (**Figure 4**)

Table 3. Healthcare resource utilization

HCRU	Patients (N = 128)
Facility, n (%)	
Standard inpatient	128 (100)
ICU	25 (19.5)
Medications[a], n (%)	
TCZ only	0 (0)
Corticosteroids only	58 (45.3)
TCZ + corticosteroids	70 (54.7)
Antibiotics	123 (96.1)
Vasopressors	17 (13.3)
Procedures, n (%)	
Dialysis	1 (0.8)
Intubation	5 (3.9)

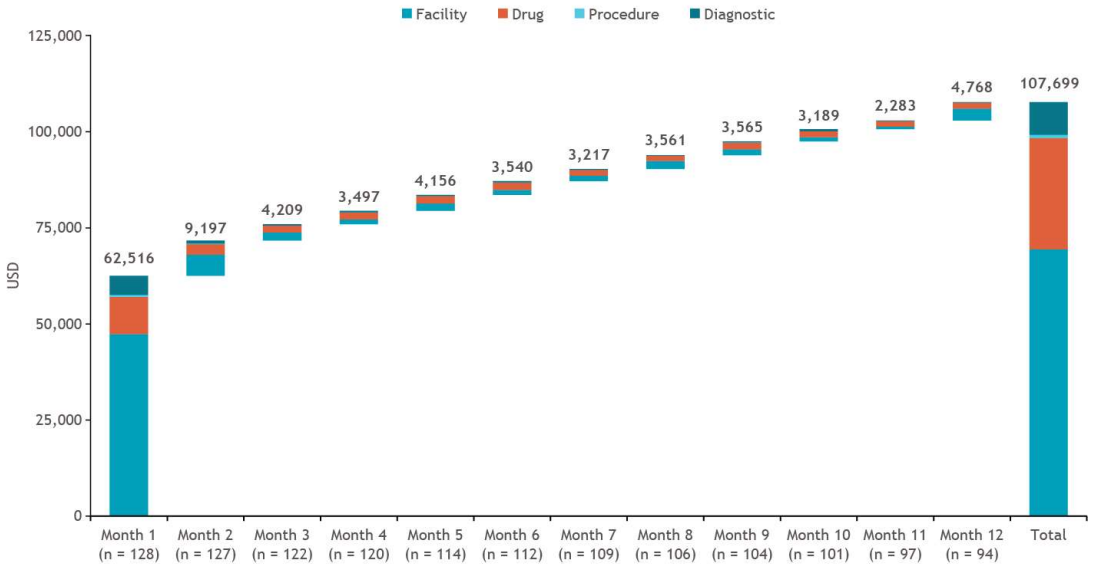
[a]Cost of ide-cel was not included in this analysis.
HCRU, healthcare resource utilization; ICU, intensive care unit; TCZ, tocilizumab.

Table 4. Length of stay

LOS	Patients (N = 128)
Standard inpatient, days	
Mean (SD)	21.4 (12.0)
Median (range)	17.5 (10-114)
ICU, days	
Mean (SD)	1.3 (3.4)
Median (range)	0 (0-24)
Total, days	
Mean (SD)	22.7 (12.5)
Median (range)	18 (15-114)

ICU, intensive care unit; LOS, length of stay; SD, standard deviation.

Figure 4. Mean cost by month post ide-cel administration[a]



[a]Cost of ide-cel was not included in this analysis.
USD, US dollars.

Limitations

- This analysis used HCRU data from a clinical trial, which may not be comparable to real-world settings
- Per the KarMMa study protocol, patients were hospitalized for 14 days after ide-cel infusion to monitor for potential adverse events, cytokine release syndrome, and neurological toxicities; therefore, cost of care may have been overestimated
  - This hospitalization period may not be necessary in routine clinical practice
- Although 27% (34/128) of patients in KarMMa were treated outside of the US, unit costs were estimated from a US provider perspective
- Due to right censoring (patient death, discontinuation, or data cutoff), cost estimates are only representative of patients with available data

CONCLUSIONS

- The estimated 1-year healthcare cost among TCE patients with RRMM treated with ide-cel in the KarMMa study was USD 107,699 (excluding the cost of ide-cel)
- A majority (58%) of costs occurred within the first month post-infusion
  - Costs plateaued after the second month
- Most patients (> 80%) did not require any ICU stay, dialysis, intubation, or vasopressors
- Hospital and ICU LOS were key drivers of 1-year costs
  - Facility costs, primarily standard inpatient stays and ICU stays accounted for 64.5% of total mean costs and were largely incurred within the first month
  - Medications (excluding ide-cel) accounted for 27.0% of total mean costs
- Ide-cel is a single-infusion BCMA-directed CAR T cell therapy associated with reduced HCRU and costs following the initial treatment period in TCE patients with RRMM

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DISCLOSURES

P.H.: Bristol Myers Squibb, Glaxo Smith Kline, Janssen, Karyopharm, Takeda – consulting. A.N., N.M., M.G.: Bristol Myers Squibb – consulting fees through employment with BluePath Solutions. K.H.: Bristol Myers Squibb – employment, stock ownership.

REFERENCES

1. Nijhof IS, et al. *Drugs* 2018;78:19-37.
2. Willson J, et al. *J Clin Oncol* 2018;36(Suppl 15):e20038.
3. Munshi NC, et al. *N Engl J Med* 2021;384:705-716.
4. Dasta JF, et al. *Crit Care Med* 2005;33:1266–1271.