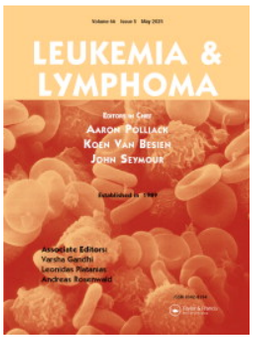

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ORIGINAL ARTICLE

Glofitamab results in cost savings versus epcoritamab in relapsed/refractory diffuse large B-cell lymphoma: a total cost of care analysis‡

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ABSTRACT

Fixed-treatment duration glofitamab and treat-to-progression epcoritamab are approved in the US for diffuse large B-cell lymphoma (DLBCL) after ≥2 prior therapies. An economic model was developed to estimate the per-patient total cost of care (TCC) for glofitamab versus epcoritamab from a US healthcare perspective. Treatment costs were based on time-to-off-treatment (glofitamab, NCT03075696) and progression-free survival (epcoritamab, NCT03625037). Per-patient cost savings, adjusted to 2023 US dollars, were observed with glofitamab versus epcoritamab across cycles 1–3 (–$56,275), and over 6 months (–$37,982), 1 year (–$68,195), 5 years (–$223,692), 10 years (–$325,175), and lifetime (–$503,075). While adverse event ($364) and treatment administration ($8,398) costs were higher for glofitamab versus epcoritamab, these were offset by consistently lower glofitamab treatment costs across all time horizons. Glofitamab showed per-patient TCC savings versus epcoritamab at every cumulative cycle and across all time horizons investigated, offering greater budget predictability and cost savings at the healthcare system and population levels.

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Glofitamab; bispecifics; epcoritamab; cost analysis; DLBCL; relapsed/refractory

Introduction

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma (NHL), accounting for about 30% of NHL cases worldwide [1]. DLBCL is a heterogeneous disease with an aggressive phenotype [2], characterized by faster progression and reduced survival compared with indolent NHL [3]. In the United States (US), the age-adjusted incidence of DLBCL was 5.6 per 100,000 per year based on 2014 to 2018 cases [4].

In relapsed/refractory (R/R) DLBCL, there is no universal standard of care, and many patients experience disease progression with available therapies or relapse following an initial response [2]. Therapy options in the third-line setting and beyond (3 L+) include chimeric antigen receptor (CAR) T-cell therapies (lisocabtagene maraleucel [5], axicabtagene ciloleucel [6], tisagenlecleucel [7]), polatuzumab vedotin plus bendamustine and rituximab [8], loncastuximab tesirine [9], epcoritamab [10], tafasitamab plus lenalidomide [11], and rituximab-based chemotherapy regimens [12,13]. Several differences exist across these therapy options, including efficacy, safety considerations, accessibility, patient eligibility, treatment course and administration method, and costs. Moreover, chemotherapy regimens can be linked to toxicities, and access to CAR T-cell therapies may be affected by manufacturing times, delivery, and location [14]. Thus, there is a need for efficacious and accessible 3 L+ therapy options for patients with R/R DLBCL.

Glofitamab is a CD20xCD3 T-cell-engaging bispecific antibody that redirects T cells to eliminate B cells by simultaneously binding to CD20 on the surface of malignant B cells and CD3 on the surface of T cells, resulting in direct activation of the T-cell response and lysis of CD20-expressing B cells [15]. Glofitamab is approved by the US Food and Drug Administration (FDA) for the treatment of adults with R/R DLBCL not otherwise specified or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy [16]. In the pivotal phase 2,

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§This affiliation was active at the time the analysis was performed.

multicenter, open-label study (NP30179; NCT03075696), glofitamab had a tolerable safety profile in patients with R/R DLBCL with grade 3/4 CRS events occurring in 4% of patients, and induced a high complete response rate of 39% [17], which was maintained with extended follow-up [18]. Epcoritamab, another bispecific CD20xCD3 T-cell-engaging antibody, also demonstrated a manageable safety profile with grade ≥3 CRS events observed in 3% patients, and a complete response rate of 39% in patients with R/R DLBCL in the phase 1/2, single-arm EPCORE NHL-1 study (NCT03625037) [10]. Similar to glofitamab, epcoritamab has been granted U.S. approval by the FDA for treatment of R/R DLBCL after two or more prior lines of systemic therapy [19]. Although these two bispecific antibodies target the same antigen and both showed comparable efficacy and safety profiles in similar populations of heavily pretreated patients with DLBCL, significant differences exist that may affect the economic outcomes of glofitamab or epcoritamab treatments.

Differences between glofitamab and epcoritamab include mode of administration (intravenous [IV] for glofitamab versus subcutaneous [SC] for epcoritamab), treatment course (≤12 cycles of fixed-duration treatment with glofitamab versus treat-to-progression with epcoritamab), frequency of administration during early cycles, and drug acquisition costs; we aimed to compare the total cost of care for the two drugs across several time horizons.

Methods

Economic model overview

In order to estimate the total cost of care for glofitamab and epcoritamab, an economic model was developed using clinical data from two clinical trials (NP30179 [17] and EPCORE NHL-1 [10]); the economic evaluation was conducted according to ISPOR-SDM Modeling Good Research Practices Task Force-2 [20]. To understand the proportion of patients on treatment over time, a partitioned survival model (also known as the area under the curve model) was built using Microsoft Excel® 2016. The mean patient age in the model was 63 years based on the glofitamab clinical study (Genentech, Data on File). Time-to-event data were used to model the proportion of patients who were in one of the three health states: progression-free, progressed disease (PD), and death. The model used a lifetime horizon of up to 60 years with a weekly cycle length [20–22]. Given that the survival data were extrapolated over a lifetime horizon, background mortality was used to ensure that the extrapolated mortality never fell below the mortality rates in the general population, and was calculated using age- and sex-specific all-cause mortality obtained from the Center for Disease Control and Prevention 2020 US life tables [23]. All costs were discounted at 3.0% per year in accordance with US guidelines [22].

Table 1. Cost categories and input estimates.

Category	Estimate
Drug costs (WAC) per vial[24]	**Glofitamab:** 2.5 mg / 2.5 mL, $2554.74 10 mg / 10 mL, $10,218.98 **Epcoritamab:** 4 mg / 0.8 mL, $1268.80 48 mg / 0.8 mL, $15,225.56
Drug administration[a][25]	**Glofitamab[b]:** $253.79 (average across all cycles) **Epcoritamab:** $97.91
Routine care (for both drugs)[c,d,] [25–27]	Year 1 (first half), $96.27 Year 1 (second half), $21.27 Year 2, $99.82 Year 3, $87.41 At progression (one-time cost), $1781.77
Weighted average costs of grade 3/4 AEs (≥5%) from USPI (excluding CRS; HCUP National Inpatient Database)[28]	**Glofitamab:** $12,049 **Epcoritamab:** $15,172
All-grade CRS from USPI[29]	**Glofitamab:** $11,519 **Epcoritamab:** $8032

AE: adverse event; CRS: cytokine release syndrome; HCUP: Healthcare Cost and Utilization Project; ICU: intensive care unit; IV: intravenous; USPI: United States Prescribing Information; WAC: wholesale acquisition cost.
[a]CRS monitoring was 100% in-patient stay for both drugs. The average amount of non-ICU hospitalizations for CRS monitoring was 1.6 stays for glofitamab. For epcoritamab, one 24-hour hospitalization after a dosage of 48 mg on C1D15 was applied in the model as per the USPI. The cost of a non-ICU hospitalization was $3315.24 [30].
[b]Drug costs for obinutuzumab pretreatment ($6694.80) were considered part of administration costs associated with glofitamab. IV infusion time was based on the USPI and took into account previous CRS.
[c]Assumed to be the same for both glofitamab and epcoritamab.
[d]Routine care cost was applied weekly in the model and included physician office visits, laboratory tests, and imaging tests over 3 years based on literature and clinical input [26].

Cost inputs

The total cost of care included the following cost categories: drug acquisition including wastage, drug administration, adverse event (AE) management, and routine care (Table 1). Subsequent treatment costs or costs associated with disease progression following glofitamab or epcoritamab treatment regimens were not included. Drug costs were based on wholesale acquisition costs (WAC) in 2023 (the time of their respective FDA approvals: May for epcoritamab and June for glofitamab) [24]. Treatment administration costs were based on the Centers for Medicare and Medicaid Services physician fee schedule from 2023 [25]. For glofitamab, IV infusion time was based on the USPI and took into account previous CRS events. Drug costs for obinutuzumab pretreatment were considered part

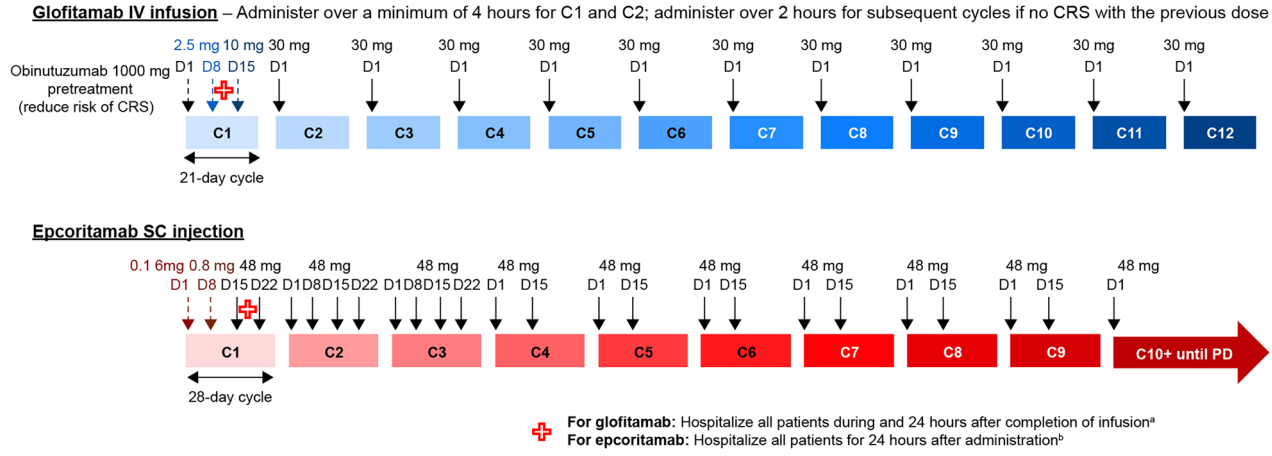

Figure 1. Treatment administration for glofitamab and epcoritamab.
C: cycle; CRS: cytokine release syndrome; D: day; IV: intravenous; SC: subcutaneous; PD: disease progression.
[a]Patients who experience any grade CRS during step-up dose 1 should be hospitalized during and for 24 hours after completion of step-up dose 2. For subsequent doses, patients who experienced grade ≥2 CRS with their previous infusion should be hospitalized during and for 24 hours after the completion of the next glofitamab infusion.
[b]Patients who experienced grade 2 CRS with their previous administration should be monitored more frequently and considered for hospitalization during their next dose of epcoritamab; those who experienced grade ≥3 CRS with their previous administration should be hospitalized for their next dose of epcoritamab.

of the administration costs associated with glofitamab. Rates of grade 3/4 AEs and cytokine release syndrome (CRS; all grades) were based on the US product prescribing information (USPI) for glofitamab and epcoritamab [31,32]. CRS monitoring occurred during an in-patient stay for both drugs. Routine care costs were assumed to be the same for both drugs and were applied weekly in the model. They included physician office visits, laboratory tests, and imaging tests based on literature and clinical input [26]. Time horizons included 6 months, 1 year, 5 years, and 10 years, as well as lifetime. Total cost of care analyses were descriptive, and results were adjusted to 2023 US dollars using the US Bureau of Labor Statistics Medical Care Consumer Price Index [33].

Treatment comparisons

Glofitamab IV was administered as a fixed-duration treatment for a maximum of 12 cycles, according to a step-up dosing schedule in cycle 1 (2.5 mg on day 8, 10 mg on day 15) and at a dose of 30 mg in cycles 2 to 12. Patients were pretreated with a single dose of obinutuzumab (1000 mg) 7 days before the first dose of glofitamab (cycle 1 day 1) to mitigate the risk of CRS. In contrast, epcoritamab SC was administered until PD and had more frequent step-up and standard dosing; cycle 1 step-up dosing consisted of a 0.16 mg priming dose on day 1, a 0.8 mg intermediate dose on day 8, and subsequent full 48 mg doses on day 15 and until PD. Epcoritamab was administered as a 1-mL injection for the 0.16 mg and 0.8 mg step-up doses once weekly until cycle 1 day 15, and as a 0.8 mL injection for the full 48 mg doses once weekly from cycle 1 day 15 to cycle 3, once every 2 weeks during cycles 4 to 9 (days 1 and 15), and once every 4 weeks from cycle 10. Full treatment administration schedules for both glofitamab and epcoritamab are shown in Figure 1.

Base case analysis

Glofitamab treatment costs were based on time-to-off-treatment (TTOT). Kaplan–Meier curves from the pivotal phase 2 trial (NP30179) [17], which take into account treatment discontinuation due to toxicity and progression. Epcoritamab treatment costs were based on progression-free survival (PFS) from the phase 1/2 dose expansion trial (EPCORE NHL-1) [10], which were extrapolated using a parametric model with a generalized gamma distribution. Epcoritamab PFS was used due to a lack of published epcoritamab TTOT Kaplan–Meier data. Cost calculations based on PFS data have been conducted in previous studies [34–36]. As available overall survival (OS) data from both trials were still likely to be immature, the model used a common survival probability for both treatments to minimize uncertainty in the estimation of total costs over time. Given that PFS is similar between glofitamab and epcoritamab and generalized gamma distribution is the best-fitting extrapolation across both drugs, the model applied the generalized gamma PFS extrapolation for epcoritamab to both comparators. Cumulative costs were examined for up to a

lifetime time horizon, where drug treatment costs (per Table 1) would be capped at 12 cycles for glofitamab and continued to PD for epcoritamab. The time horizon for the model in the base case included 6 months,1 year, 5 years, and 10 years.

Scenario analysis

In a scenario analysis, the cost of glofitamab treatment was calculated using PFS (versus TTOT, as used in the base case). Similar to the base case, the model applied the generalized gamma PFS extrapolation for epcoritamab to both comparators, and drug treatment costs were capped at 12 cycles for glofitamab. The time horizon for the model in the scenario analyses included 6 months,1 year, 5 years, and 10 years.

Results

Patients

The patient population used in the model included 155 patients from the NP30179 study receiving glofitamab and 157 patients from the EPCORE NHL-1 study receiving epcoritamab. Details on patient demographics and disease characteristics of these two study populations have previously been published [10,17].

Base case analysis

Glofitamab was less costly than epcoritamab across all cumulative treatment cycles (Figure 2). Epcoritamab had higher upfront costs compared with glofitamab, with $56,275 higher cumulative costs across cycles 1 to 3 ($95,904 for glofitamab versus $152,179 for epcoritamab) when epcoritamab had its most frequent dosing per cycle. Per-patient cost savings were also observed for glofitamab versus epcoritamab over all time horizons (Table 2), including 6 months (–$37,982), 1 year (–$68,195), 5 years (–$223,692), 10 years (–$325,175), and over the lifetime (–$503,075). Although AE costs (including CRS) and treatment administration costs were slightly higher for glofitamab ($23,569 and $13,276, respectively) compared with epcoritamab ($23,204 and $4,675, respectively) across all time horizons, this was offset by the lower treatment costs across all time horizons for glofitamab versus epcoritamab.

Scenario analysis

Consistent with the observations in the base case, the scenario analysis demonstrated that total cost of care was lower with glofitamab versus epcoritamab. In the scenario analysis, the cumulative cost of care across cycles was higher for epcoritamab compared with glofitamab (Figure 3). Differences in per-patient cost savings for glofitamab were observed across all time horizons, including 6 months (–$7,588), 1 year (–$21,708), 5 years (–$177,206), 10 years (–$278,688), and over the lifetime (–$456,588) (Table 3). Cost savings associated with glofitamab were reduced when using PFS compared with using TTOT in the base case, the latter of

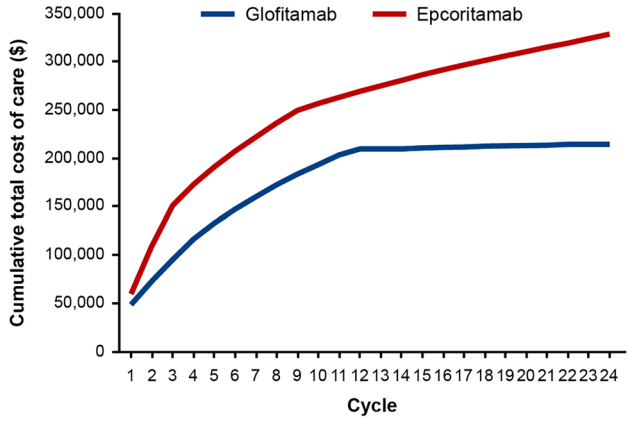

Figure 2. Base case: cumulative total cost of care for glofitamab versus epcoritamab across treatment cycles.

Table 2. Base case: differences in total costs of care between glofitamab and epcoritamab across various time horizons.

	6-month		1-year		5-year		10-year		Lifetime	
	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor
Total costs	$176,310	$214,291	$200,829	$269,024	$207,350	$431,042	$210,597	$535,772	$214,924	$717,999
Difference[a]	–$37,982		–$68,195		–$233,692		–$325,175		–$503,075	
Drug	$136,928	$183,874	$160,737	$237,695	$160,737	$392,199	$160,737	$493,033	$160,737	$669,796
Difference[a]	–$46,947		–$76,958		–$231,462		–$332,296		–$509,059	
Treatment administration	$13,276	$4675	$13,419	$5021	$13,419	$6015	$13,419	$6663	$13,419	$7800
Difference[a]	$8601		$8398		$7405		$6756		$5620	
AEs	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204
Difference[a]	$364		$364		$364		$364		$364	
Routine care	$2538	$2538	$3104	$3104	$9625	$9625	$12,872	$12,872	$17,199	$17,199
Difference[a]	$0		$0		$0		$0		$0	

AEs: adverse event; Epcor: epcoritamab; Glofit, glofitamab.
[a]Glofitamab versus epcoritamab.

which included treatment discontinuation for reasons beyond progression only and, therefore, reflected a shorter average time on treatment.

Discussion

Patients with R/R DLBCL represent a population with a significant unmet need; glofitamab and epcoritamab are recently approved treatment options for patients with R/R DLBCL after two or more prior lines of therapy. Glofitamab and epcoritamab possess many similarities, such as both targeting the same antigen and having comparable efficacy and safety profiles [37]; as such, this analysis aimed to compare the total cost of care for the two drugs across several time horizons.

Our analysis showed that glofitamab had lower upfront costs, particularly in the first few cycles when epcoritamab dosing was more frequent (four injections per cycle). The lower total costs with glofitamab can be attributed to lower annual drug acquisition costs, fixed-duration treatment with a maximum of 12 cycles, and less frequent dosing in earlier cycles. AE (including CRS) costs were slightly higher for glofitamab versus epcoritamab ($364); however, this was offset by the lower treatment costs for glofitamab. The cost savings associated with glofitamab were reduced when using PFS in the scenario analysis compared with using TTOT in the base case, as the former included treatment discontinuation due to progression only, reflecting a longer average time on treatment. The conclusions of the scenario analysis were consistent with the base case that glofitamab had lower total costs of care versus epcoritamab.

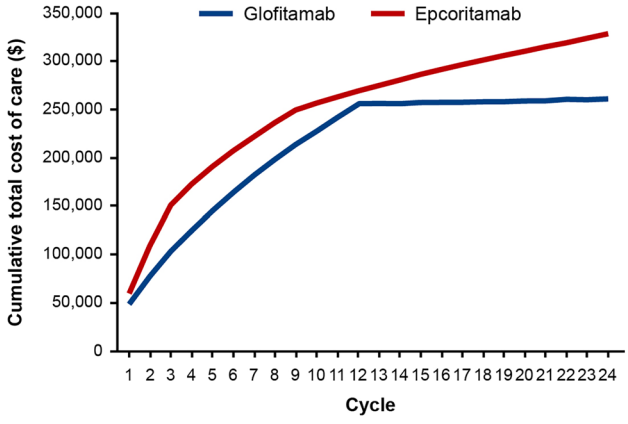

Figure 3. Scenario analysis: cumulative total cost of care for glofitamab versus epcoritamab across treatment cycles.

Although epcoritamab costs are higher than glofitamab, bispecific therapies such as these drugs offer accessibility and cost savings over other therapy options for 3L+DLBCL, such as CAR T-cell therapies. CAR T-cell therapies are often inaccessible to many patients due to the high associated costs or administrative challenges [38]. The mean total cost of care for patients receiving CAR T-cell therapies within 3 months from infusion can range from $379,627 to $525,772, and higher costs (up to $679,195) were associated with the presence of AEs [39]. In this analysis, the total cost of care for glofitamab was lower than CAR T-cell therapies at every time horizon ($176,310 to $261,411), whereas epcoritamab ranged from $214,291 to $717,999. Although, it should be noted that the cost of care for CAR T-cell therapy includes 3 months post-infusion, whereas the upper limit of epcoritamab ($717,999) from this analysis is the lifetime cost.

To our knowledge, this is the first total cost of care analysis of the glofitamab versus epcoritamab treatment regimens in the U.S. The model results were generally robust across the base case and scenario analyses tested. Further, the data from this analysis can help payers and healthcare systems with decision-making about the use of bispecifics in R/R DLBCL.

A limitation of this study was that only one fitted parametric model was used for these analyses. However, the best-fitted parametric model was implemented, and given that a large proportion of cost savings are accrued during the first few treatment cycles for which observed

Table 3. Scenario analysis: differences in total costs of care between glofitamab and epcoritamab across various time horizons.

	6-month		1-year		5-year		10-year		Lifetime	
	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor	Glofit	Epcor
Total costs	$206,704	$214,291	$247,316	$269,024	$253,836	$431,042	$257,084	$535,772	$261,411	$717,999
Difference[a]	−$7588		−$21,708		−$177,206		−$278,688		−$456,588	
Drug	$166,733	$183,874	$206,539	$237,695	$206,539	$392,199	$206,539	$493,033	$206,539	$669,796
Difference[a]	−$17,141		−$31,156		−$185,660		−$286,494		−$463,257	
Treatment administration	$13,864	$4675	$14,104	$5021	$14,104	$6015	$14,104	$6663	$14,104	$7800
Difference[a]	$9189		$9083		$8090		$7441		$6304	
AEs	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204	$23,569	$23,204
Difference[a]	$364		$364		$364		$364		$364	
Routine care	$2538	$2538	$3104	$3104	$9625	$9625	$12,872	$12,872	$17,199	$17,199
Difference[a]	$0		$0		$0		$0		$0	

AE: adverse event; Epcor: epcoritamab; Glofit: glofitamab.
[a]Glofitamab versus epcoritamab.

data are available, it is unlikely that the choice of parametric extrapolation model would have drastically altered the conclusions. In addition, as OS data were immature for both glofitamab and epcoritamab, the same OS probability curves were used for both treatments, and as such, the analysis did not capture any differences in survival. Only direct costs were considered. Indirect costs related to the dosing schedule were not included and may be higher for epcoritamab, given the more frequent administration schedule and treat-to-progression regimen. Also, other indirect costs such as the economic burden of R/R DLBCL (e.g. related to caregivers) were not captured; therefore, our estimates are possibly conservative. In addition, the analysis only examined glofitamab and epcoritamab costs and not clinical outcomes or subsequent treatment costs. Costs may differ in the real world because dosing inputs were taken from the clinical trial or USPI for both drugs. Finally, as this analysis focuses on direct costs from the healthcare payer perspective, broader health system impacts of subcutaneous injections and infusion center throughput are not captured.

Conclusions

In summary, glofitamab resulted in per-patient cost savings compared with epcoritamab at every cumulative administration cycle, particularly in the first few cycles when epcoritamab has more frequent dosing per cycle than glofitamab. While treatment administration costs were higher, and AE costs were slightly higher with glofitamab, the lower total cost of care with glofitamab across all time horizons can be attributed to the lower annual drug acquisition costs, fixed-duration treatment with a maximum of 12 cycles, and less frequent dosing in earlier cycles. With lower drug costs overall, glofitamab, with its fixed-duration regimen, offers greater healthcare budget predictability versus epcoritamab, which is expected to translate to cost savings at the broader healthcare system and population levels.

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Conception and design: Katherine L. Rosettie, Anthony Masaquel, Jia Li, Zahra Mahmoudjafari, Danilo Di Maio

Provision of study materials or patients: Danilo Di Maio

Collection and assembly of data: Anthony Masaquel

Data analysis and interpretation: Katherine L. Rosettie, Anthony Masaquel, Jia Li, Zahra Mahmoudjafari

Manuscript writing: Katherine L. Rosettie, Anthony Masaquel, Jia Li, Zahra Mahmoudjafari, Danilo Di Maio

Final approval of manuscript: Katherine L. Rosettie, Anthony Masaquel, Jia Li, Zahra Mahmoudjafari, Danilo Di Maio

Accountable for all aspects of the work: Anthony Masaquel

Disclosure of interest

Z.M. reports consultancy including expert testimony (Genentech, Inc.); and honoraria for advisory board participation (Genentech, Inc., KITE, BMS, AstraZeneca, Pfizer, Janssen). D.D.M. is employed by and a current equity holder in a publicly traded company (F. Hoffmann-La Roche Ltd). J.L. was employed by Genentech, Inc. at the time of the analysis. K.L.R. is employed by Genentech, Inc.; ended employment at IQVIA in the past 24 months (IQVIA); and is a current equity holder in a publicly traded company (F. Hoffmann-La Roche Ltd). A.M. is employed by Genentech, Inc.; and is a current equity holder in a publicly traded company (F. Hoffmann-La Roche Ltd).

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Data availability statement

Qualified researchers may request access to individual patient-level data through the clinical study data request platform (https://vivli.org/). Further details on Roche's criteria for eligible studies are available at https://vivli.org/members/ourmembers/. For further details on Roche's Global Policy on the Sharing of Clinical Information and how to request access to related clinical study documents, see https://www.roche.com/research_and_development/who_we_are_how_we_work/clinical_trials/our_commitment_to_data_sharing.htm.

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