EE150

A Budget Impact Analysis of the Introduction of Mosunetuzumab for Treatment of Third- or Higher-line (3L+) Relapsed or Refractory (R/R) Follicular Lymphoma (FL) in the United States (US)

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Summary

Mosunetuzumab (Mosun) has received approval from the US Food and Drug Administration for the treatment of R/R 3L+ FL. A budget impact analysis was conducted to assess the impact of introducing Mosun as a treatment in the US

The cost per patient in the model consisted of drug costs, including wastage, drug administration (admin), and adverse events, and routine care

Fixed-duration Mosun treatment offers cost savings compared with most other novel drugs for R/R 3L+ FL and has minimal budget impact on a US health plan over a 3-year time period

Mosun had the second lowest cumulative per patient and drug cost amongst other novel therapies. This resulted in an average incremental per-member per-month (PMPM) budget impact of $0.0019 over 3 years

Conclusions

- Fixed treatment duration with Mosun offers cost savings over most other novel therapies, ranging from a 19–60% reduction in total cumulative per patient costs over 3 years.
- Providing access to Mosun for the treatment of adult patients with R/R 3L+ FL showed minimal budget impact on a US health plan over a 3-year time horizon.

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Background

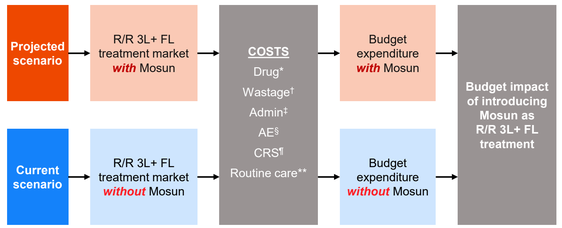
- FL is the second-most common lymphoma and accounts for approximately 35% of all non-Hodgkin lymphomas (NHLs).[1]
- Despite being classified as indolent, FL is not curable with current therapies. Most patients experience relapses and face a risk of transformation to aggressive lymphoma, which is associated with poor outcomes.[1,2]
- Mosun, an intravenously-administered CD20xCD3 T-cell engaging bispecific antibody, has received accelerated approval by the US FDA for the treatment of adult patients with R/R FL after two or more lines of systemic therapy.[3,4]
- The aim of this study was to assess the budget impact of introducing Mosun as a R/R 3L+ FL treatment option and to estimate the total cumulative costs per patient vs relevant comparators in the US.

Methods

Model overview

- A 3-year budget impact model (BIM) was developed to compare two different potential scenarios (**Figure 1**).
- The model calculated costs per patient per regimen and included costs of the drug, wastage, and admin, adverse events (AEs), cytokine release syndrome (CRS), and management costs associated with FL (**Figure 1**).
- Costs were standardized to 2022 US Dollars (USD)[5] except for drug acquisition costs which were current as of March 2023.[6]

Figure 1. Budget impact model structure.



*Calculated based on wholesale acquisition costs, dosing schedule, and mean treatment duration from US package inserts (PIs), routine clinical practice and clinical trial data. †For intravenous (IV) drugs only; wastage resultant from discrepancy between vial size and actual dosage. ‡For IV drugs, based on resources associated with time needed to administer the drug, taking into account information on dosing and infusion rate found in US PIs. For axicabtagene ciloleucel (axi-cel) and tisagenlecleucel (tisa-cel), these accounted for leukapheresis, drug admin, conditioning chemotherapy, and hospitalization. §Calculated based on rates of Grade ≥3 severity occurring in ≥5% of patients treated with any comparator, as reported in US PIs, clinical trial data, and unit costs from Healthcare Cost and Utilization Project. ¶For Mosun, axi-cel, and tisa-cel, these were based on CRS rates of any severity and associated resources (hospitalization and tocilizumab treatment). Frequencies and costs were sourced from US PIs, clinical trial data, and published literature. **Comprised FL management costs associated with routine clinical practice. Frequencies were sourced from expert opinion; costs extracted from Centers for Medicare and Medicaid Services fee schedules.

Model inputs

- Inputs to identify the annual number of patients eligible for Mosun in a hypothetical cohort of 1 million members enrolled in a mixed Commercial/Medicare health plan are detailed in **Table 1**.
- The BIM assumed that 54.1% of eligible patients were covered by Medicare.[7]
- Comparators included in the model were: axi-cel, tisa-cel, rituximab + lenalidomide (R-Len), tazemetostat (taz), copanlisib (copan), and older therapies (rituximab or obinutuzumab ± chemotherapy) **(Table 2)**.
- Patients were distributed to different regimens according to specified market shares that were based on Genentech projections and expert opinion.[7]
- The market uptake of Mosun was assumed to be 25%, 30%, and 35%, in the first, second, and third year of the model, respectively.[7]

Table 1. Target population identification inputs.

Parameter	Value	Source
Health plan population, n	1,000,000	Assumption
Proportion of plan members aged ≥18 years old (%)	77.7	US Census Bureau[8]
Proportion of adult plan members aged		
18–64 years old (%)	78.9	US Census Bureau[8]
≥65 years old (%)	21.2	US Census Bureau[8]
NHL prevalence rate		
18–64 years old (%)	0.1358	SEER[9]
≥65 years old (%)	0.8821	SEER[9]
Proportion of NHL which are FL (%)	20.0	National Cancer Institute[2]
Proportion of NHL which are R/R 3L+ (%)	2.2	Link et al. 2019[10]

SEER, National Cancer Institute Surveillance, Epidemiology and End Results Program.

Table 2. Drug acquisition costs and treatment duration.

Regimen*	Strength package size	WAC package cost ($)	Treatment duration (cycle)
Mosun	1mg/mL, 1mL 1mg/mL, 30mL	594.06 17,821.78	8.0†
Axi-cel	N/A	424,000.00	1.0‡
Tisa-cel	N/A	427,047.70	1.0‡
R-Len	R: 10mg/mL, 10mL Len: 20mg, 21 cap	824.24 17,497.73	5.0§ 11.2
Taz	200mg, 240 tab	18,850.00	14.0¶
Copan	60mg, vial	5,049.60	7.1**

*Dosing was sourced from respective package inserts. †Mean duration aligned with the trial.[7] ‡For axi-cel and tisa-cel, treatment is a single infusion.[11,12] §Duration of lenalidomide based on median duration reported in the trial[13] while the duration of rituximab was unknown and assumed equal to the full course (i.e. 5 cycles). ¶Mean duration in 28-day cycles estimated from the median duration in months[14] using a previously published approach.[15] **Mean duration aligned with the trial.[16]
cap, capsule; N/A, not applicable; tab, tablet; WAC, wholesale acquisition cost.

Model outputs (cont.)

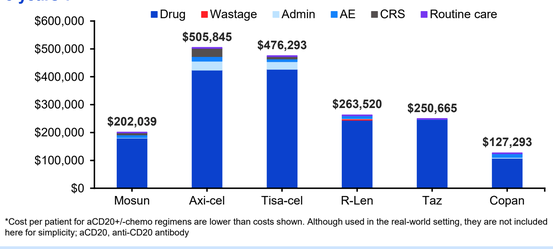
- Total and itemized per patient cost outcomes were reported cumulatively over 3 years for Mosun and other novel therapies.
- Budget impact outcomes were presented as absolute and incremental PMPM for each of the first 3 years and cumulatively over the 3-year time period.
- Sensitivity analyses were conducted around the budget impact, including a deterministic sensitivity analysis and scenario analyses.

Results

Per patient cost

- Mosun had the second lowest total cumulative per patient and drug cost among other novel therapies included in the BIM (**Figure 2**).
- The cumulative difference over 3 years in per patient cost amounted to savings of $303,805 with Mosun vs axi-cel, $274,254 vs tisa-cel, $61,481 vs R-Len, $48,625 vs taz, and a cost increase of $74,747 vs copan (**Figure 2**).

Figure 2. Comparison of cumulative costs per patient per regimen over 3 years*.



*Cost per patient for aCD20+/-chemo regimens are lower than costs shown. Although used in the real-world setting, they are not included here for simplicity; aCD20, anti-CD20 antibody

Budget impact

- In the hypothetical health plan encompassing 1 million lives, the annual number of patients eligible for Mosun was estimated to be 10.
- The introduction of Mosun to the R/R 3L+ FL treatment landscape resulted in an increase in budget of $69,812, translating to an average incremental PMPM of $0.0019 over 3 years (**Table 3**).

Table 3. Total budget in the current vs projected scenario and budget impact.

Budget impact	Without Mosun (current scenario)	With Mosun (projected scenario)	Incremental
Total budget ($)	6,943,372	7,013,184	69,812
Average PMPM ($)	0.1929	0.1948	0.0019
Breakdown of total budget by year			
Year 1 ($)	2,258,357	2,318,953	60,596
Year 2 ($)	2,336,526	2,332,943	-3,583
Year 3 ($)	2,348,489	2,361,288	12,799

Scenario and sensitivity analyses

- The scenario analyses results were consistent with base case findings (**Figure 3** and **Table 4**).
- Across all sensitivity and scenario analyses, the inclusion of Mosun had a minimal impact on the PMPM cost, ranging from -$0.0002 to $0.0115 compared with $0.0019 in the base case.

Figure 3. Tornado diagram of one-way sensitivity analyses on net PMPM budget impact over 3 years.

Table 4. Key scenario analyses.

Scenario	Total budget impact ($)	Average PMPM ($)
1-year time horizon	60,596	0.0050
Alternative source for share of FL which are R/R 3L+[16]	140,803	0.0039
Full course of treatment for all regimens*	414,626	0.0115
Routine care costs based on broader OP costs[7]	-6,781	-0.0002
Payer channel:		
100% Medicare	213,675	0.0059
100% Commercial	31,583	0.0009

*For Mosun, the full course of treatment is set to 17 cycles which is an overestimation of the treatment duration as patients who achieved a complete response do not require further treatment beyond 8 cycles. OP, outpatient.

Limitations

- Discounts on drug list prices were excluded, which may impact the incremental cost associated with the entry of Mosun.
- Market penetration estimates were based on Genentech internal projections and may be subject to uncertainty.
- Compliance, post-discontinuation treatment, and mortality were not assessed.
- Model inputs were based on multiple data sources and some assumptions. Therefore, uncertainty was assessed in sensitivity analyses.

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