Budget Impact Analysis of Introduction of Rituximab Biosimilar in the United States from a Payer Perspective

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INTRODUCTION

- Rituximab-pvvr, a biosimilar of intravenously (IV) administered rituximab, was approved by FDA for the treatment of follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA), and microscopic polyangiitis (MPA).[1]
- Rituximab is among one of the top three drug expenditures in the US for Medicare Part B program throughout 2013-2017 with an annual growth rate of 5% in drug unit cost.[2] Rituximab biosimilar therefore presents a viable option for cost-savings in oncology patients.
- A BIA conducted in 28 European countries estimated that rituximab biosimilar would be associated with a budget saving of €90 million in the first year, assuming a biosimilar discount of 30% and an uptake of 30%.[3]
- The present study conducted a budget impact analysis (BIA) to understand the potential financial effect of introducing rituximab-pvvr in a US health plan.

METHODS

- A BIA was developed using Microsoft Excel to evaluate the budget impact of rituximab-pvvr over a 3-year time frame from a US payer perspective by comparing the total budget between market scenarios without and with rituximab-pvvr.
- Target population was patients to be treated with rituximab (IV rituximab, or subcutaneous rituximab and hyaluronidase human) for approved indications, estimated based on published literature.
- Comparators to rituximab -pvvr in this analysis were rituximab biologics, included IV rituximab and SC rituximab and hyaluronidase human (SC rituximab)
- In the scenario without rituximab -pvvr, it was assumed that the market share was evenly distributed between IV Rituximab and SC Rituximab in lymphomas (including FL, DLBCL, and CLL).
- Because SC rituximab is not indicated for treatment of auto -immune diseases (including GPA and MPA) in the US, IV rituximab accounted for 100% of the market share in auto-immune diseases (including GPA and MPA) prior to introduction of rituximab-pvvr, assuming no off-label use of SC rituximab.
- In the scenario with rituximab -pvvr, uptake of rituximab-pvvr was assumed to increase in a linear fashion following its market entry, resulting in an uptake of 23%, 46% and 70% in year 1 to 3.
- Drug costs of rituximab originators were based on average sales price (ASP) ($944 per 100mg for IV rituximab and $6,002 per 1400mg for SC rituximab),[4] with a 6% mark-up.
- A discount of 20% was applied for rituximab-pvvr relative to IV rituximab cost. Drug cost of rituximab-pvvr was estimated estimated as rituximab-pvvr ASP plus 6% of the ASP of originator, IV rituximab.[5]
- Administration cost was based on the Medicare Physician Fee Schedule.[6]
- Scenario analyses were conducted to test the model robustness.

RESULTS

- In a hypothetical 10-million-member health plan, 754 patients were estimated to be treated with rituximab originators or biosimilar in year 1 and 764 patients in year 3 (**Table 1**).
- Switching from originators to rituximab-pvvr resulted in a total cost saving of $1,226,292 in year 1 ($0.01 per member per month [PMPM], $1,625 per patient per year [PPPY]) and $3,779,047 in year 3 ($0.03 PMPM, $4,947 PPPY) (**Table 1**).
- The total budget impact was primarily driven by that in DLBCL population, followed by untreated FL and CLL populations (**Figure 1**).
- Varying biosimilar discount to 15% and 40% resulted in a cost saving of $792,865 and $2,960,004 respectively in year 1 (**Table 2**).
- Increasing ASP markup to 10% resulted in a cost saving of $1,208,964 (**Table 2**).
- In the scenario where no vial sharing was assumed, the cost saving decreased to $1,133,991 in year 1 (**Table 2**).

RESULTS (cont'd)

Figure 1. Total Incremental Budget Impact in Base Case Analysis, By Indication

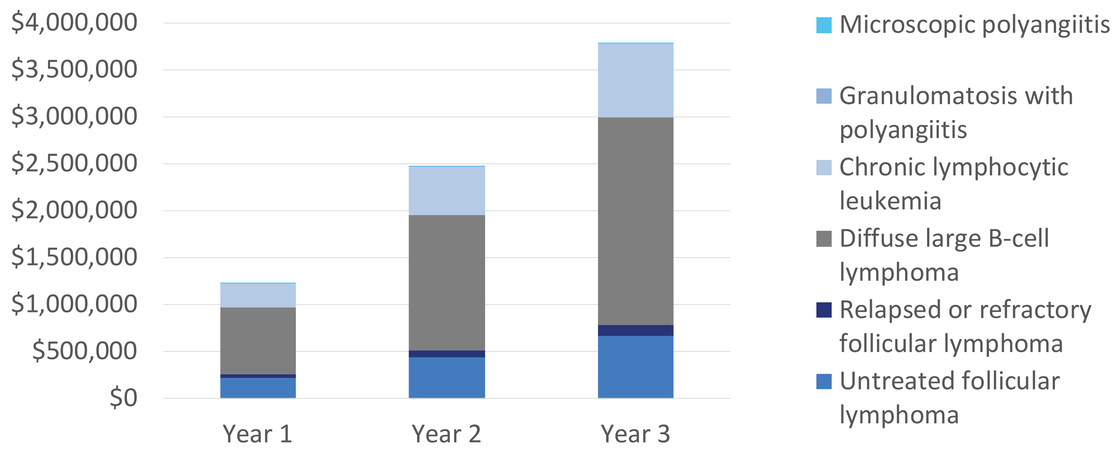

Table 1. Base Case Results

	Year 1	Year 2	Year 3
Rituximab originator- or biosimilar-treated patients	754	759	764
Total Costs			
Total costs in market without rituximab-pvvr	$38,651,785	$38,893,637	$39,137,002
Drug cost	$37,954,195	$38,191,682	$38,430,655
Administration cost	$697,590	$701,955	$706,347
Total costs in market with rituximab-pvvr	$37,425,492	$36,425,705	$35,357,955
Drug cost	$36,679,690	$35,626,722	$34,503,031
Administration cost	$745,803	$798,984	$854,924
Incremental budget impact results			
Cost savings in total	$1,226,292	$2,467,931	$3,779,047
Cost savings PPPY	$1,625	$3,251	$4,947
Cost savings PPPM	$135	$271	$412
Cost savings PMPY	$0.12	$0.25	$0.37
Cost savings PMPM	$0.01	$0.02	$0.03

PMPY, per member per year; PMPM, per member per month; PPPM, per patient per month; PPPY, per patient per year

Table 2. Sensitivity Analyses Results

	Year 1	Year 2	Year 3
Scenario: rituximab-pvvr discount of 15% relative to IV rituximab (20% in base case)			
Total costs in market without bevacizumab-bvzr	$37,858,920	$37,297,985	$36,693,643
Total costs in market with bevacizumab-bvzr	$38,651,785	$38,893,637	$39,137,002
Cost savings in total	$792,865	$1,595,651	$2,443,359
Scenario: rituximab-pvvr discount of 40% relative to IV rituximab (20% in base case)			
Total costs in market without bevacizumab-bvzr	$35,691,781	$32,936,586	$30,015,203
Total costs in market with bevacizumab-bvzr	$38,651,785	$38,893,637	$39,137,002
Cost savings in total	$2,960,004	$5,957,051	$9,121,799
Scenario: no vial sharing (vial sharing in base case)			
Total costs in market without bevacizumab-bvzr	$38,279,413	$37,377,848	$36,413,580
Total costs in market with bevacizumab-bvzr	$39,413,404	$39,660,021	$39,908,182
Cost savings in total	$1,133,991	$2,282,173	$3,494,602
Scenario: reimbursement markup of 10% relative to average sales price (6% in base case)			
Total costs in market without bevacizumab-bvzr	$38,875,055	$37,901,775	$36,861,570
Total costs in market with bevacizumab-bvzr	$40,084,019	$40,334,832	$40,587,215
Cost savings in total	$1,208,964	$2,433,057	$3,725,646

CONCLUSIONS

The results suggest a potential cost saving with switching from rituximab originators to biosimilar rituximab-pvvr, primarily driven by lower cost of rituximab-pvvr. The exact cost saving estimates may vary depending on extra drug rebates and proportion of patients switching to rituximab-pvvr

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