

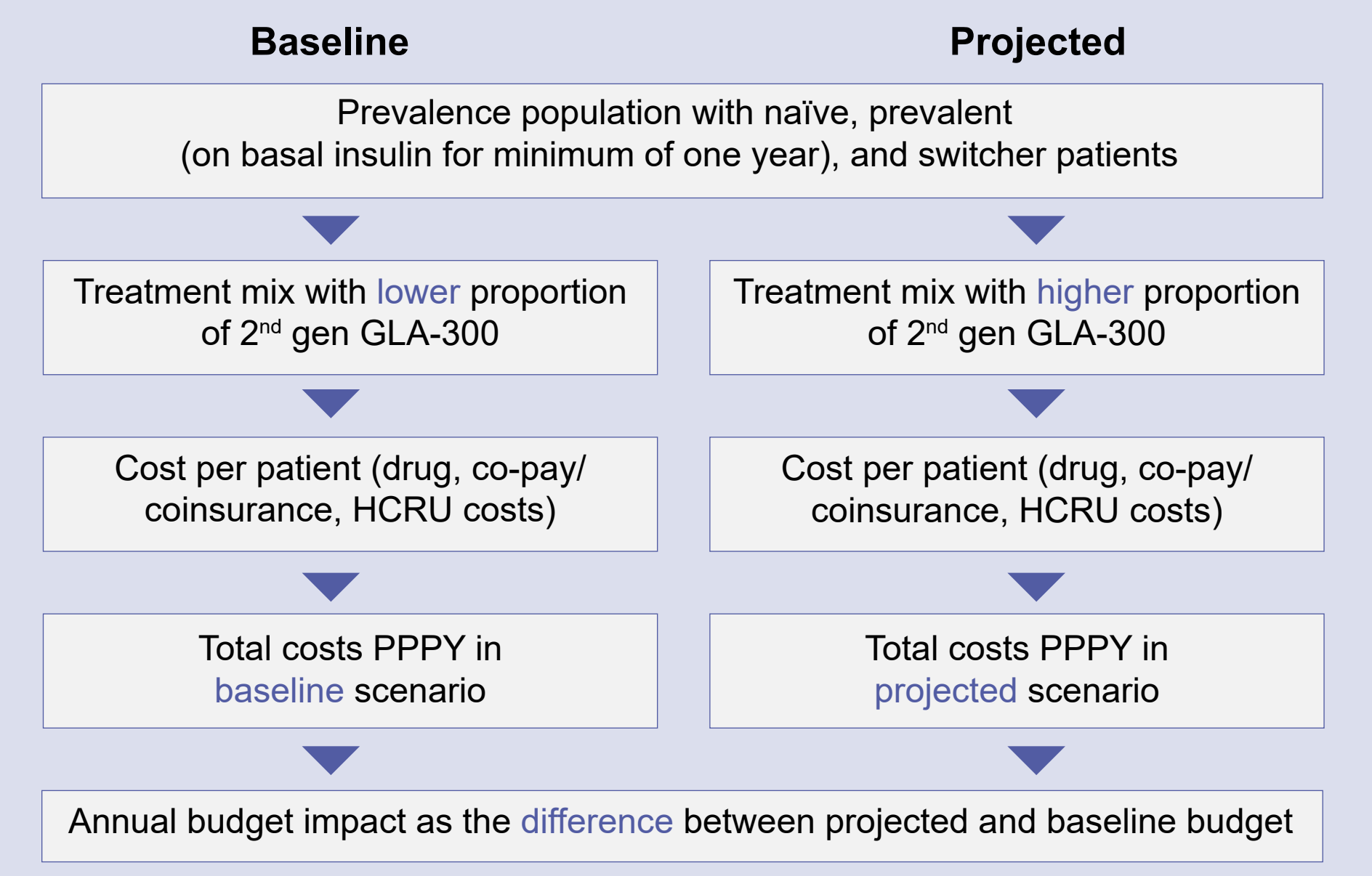
The Economic Value Of Insulin Glargine 300 U/MI (GLA-300) In People ≥18 Years of Age With Type 2 Diabetes Mellitus: A Value-based Economic Model From A U.S. Payer Perspective

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BACKGROUND AND OBJECTIVES

- T2DM has emerged as a major public health issue due to its high impact on morbidity, mortality, and healthcare resources¹
- Treatments for T2DM include oral anti-diabetics, glucagon-like peptide 1 (GLP1s) receptor agonists, daily basal insulins, and regular insulin with meals²
- 2nd generation (gen) basal insulin analogues (insulin glargine 300 U/mL [Gla-300]) have demonstrated similar efficacy in reducing HbA1c to 1st generation (gen) insulin therapy (e.g., insulin glargine 100 U/mL [Gla-100]) along with lower risk of hypoglycemia⁴
- This value-based budget impact model (BIM) incorporates real-world evidence (RWE) to demonstrate the value and affordability of Gla-300 for the treatment of adult patients with T2DM receiving BIs from a U.S. payer perspective. The model framework is presented below in **Figure 1**

Figure 1. Framework of budget impact model



METHODS

- The economic impact of switching from 1st gen BIs to 2nd gen BIs was calculated using a BIM developed in Microsoft Excel 2010 (Microsoft Corp, Redmond, WA)
- The baseline market shares for 1st gen and 2nd gen BIs were obtained from Sanofi Internal (Data on File)⁷, which were used for projecting the market shares for years 1, 2, and 3
- A prevalence-based modelling approach was employed, consisting of three types of patients receiving BIs obtained using RWE: prevalent patients (have been on insulin treatment for at least one year), naïve patients (new to the BI treatment, less than one year), switchers (previously naïve or prevalent patients who have switched insulin treatments) (**Figure 2**):
 - Prevalent patients (have been on insulin treatment for at least one year)
 - Naïve patients (new to the BI treatment, less than one year)
 - Switchers (previously naïve or prevalent patients who have switched insulin treatments)
- The model assessed the cost of treatment (drug costs), hypoglycemic events (associated with emergency, inpatient, and outpatient visits), and diabetes-related healthcare resource utilization (HCRU) costs (associated with emergency, inpatient, and outpatient visits) and its frequency obtained using RWE^{9,10}

MODEL ASSUMPTIONS

- Annual plan population growth rate was considered as 4% and assumed to be the same across the model time horizon
- A hypothetical plan population of 1 million patients, in which the proportion of patients having T2DM⁴ aligned with observed prevalence in the US adult population
- Treatments for T2DM patients were assumed to be 1st gen BIs, 2nd gen BIs, (insulin glargine-Gla-300), degludec and insulin glargine biosimilars⁵
- The model does not include degludec in 2nd gen BIs but allows the patients to switch from 1st gen to insulin degludec. This is done to separate out the effect of degludec from the study insulin as previously done for 2019 lightning study⁸
- Glargine biosimilars are not included in 1st gen BIs. Since the market share of glargine biosimilar is predicted to increase over a period in the real-world clinical practice in contrast to 1st gen BIs
- The proportion of T2DM patients who were not naïve⁶ and non-switcher were assumed to be prevalent patients (who continued the same basal insulins without switching) and the methodology used is consistent with the 2019 lightning study⁸
- The analysis did not consider switchers at baseline
- In the base case scenario, patients switched from 1st gen BIs from baseline year to 2nd gen BIs by projected year 3. Model also considers the scenario where patients switched from 2nd gen BIs from baseline year to 1st gen BIs by projected year 3
- In the baseline year 62.7% of patients were naïve
- Initiating from baseline year, 23% of patients switched to insulin glargine biosimilars by projected year 3
- Due to a lack of data, HCRU for the prevalent population was assumed to be a weighted average of the naïve and switcher populations (**Table 1**)

Table 1. Baseline HCRU costs

	HCRU	Unit Cost (2021 \$) ¹⁵
Inpatient Visit (Per Day)	All cause ¹¹	\$2,884.70
	Diabetes Related ¹¹	\$2,493.81
	Hypoglycemia Related ¹¹	\$2,676.50
ED Visit	All Cause ¹²	\$1,277.58
	Diabetes Related ¹²	\$1,159.58
	Hypoglycemia Related ¹³	\$2,020.20
Outpatient Visit	All Cause ¹⁴	\$84.00
	Diabetes Related ¹³	\$163.56
	Hypoglycemia Related ¹³	\$573.76

Table 2. Base case market shares (%)

1 st gen to 2 nd gen switch	Baseline market shares	Projected market shares			
Insulin	Y0	Y1	Y2	Y3	
2 nd gen BIs	6.69%	7.15%	7.92%	8.22%	
1 st gen Bis	80.52%	75.25%	68.20%	56.80%	
Glargine biosimilars	0.10%	5.04%	11.54%	22.72%	
Insulin degludec	12.69%	12.56%	12.34%	12.26%	
Total	100.00%	100.00%	100.00%	100.00%	

Abbreviation; BIs: Basal Insulins

Figure 2. Patient type flowchart

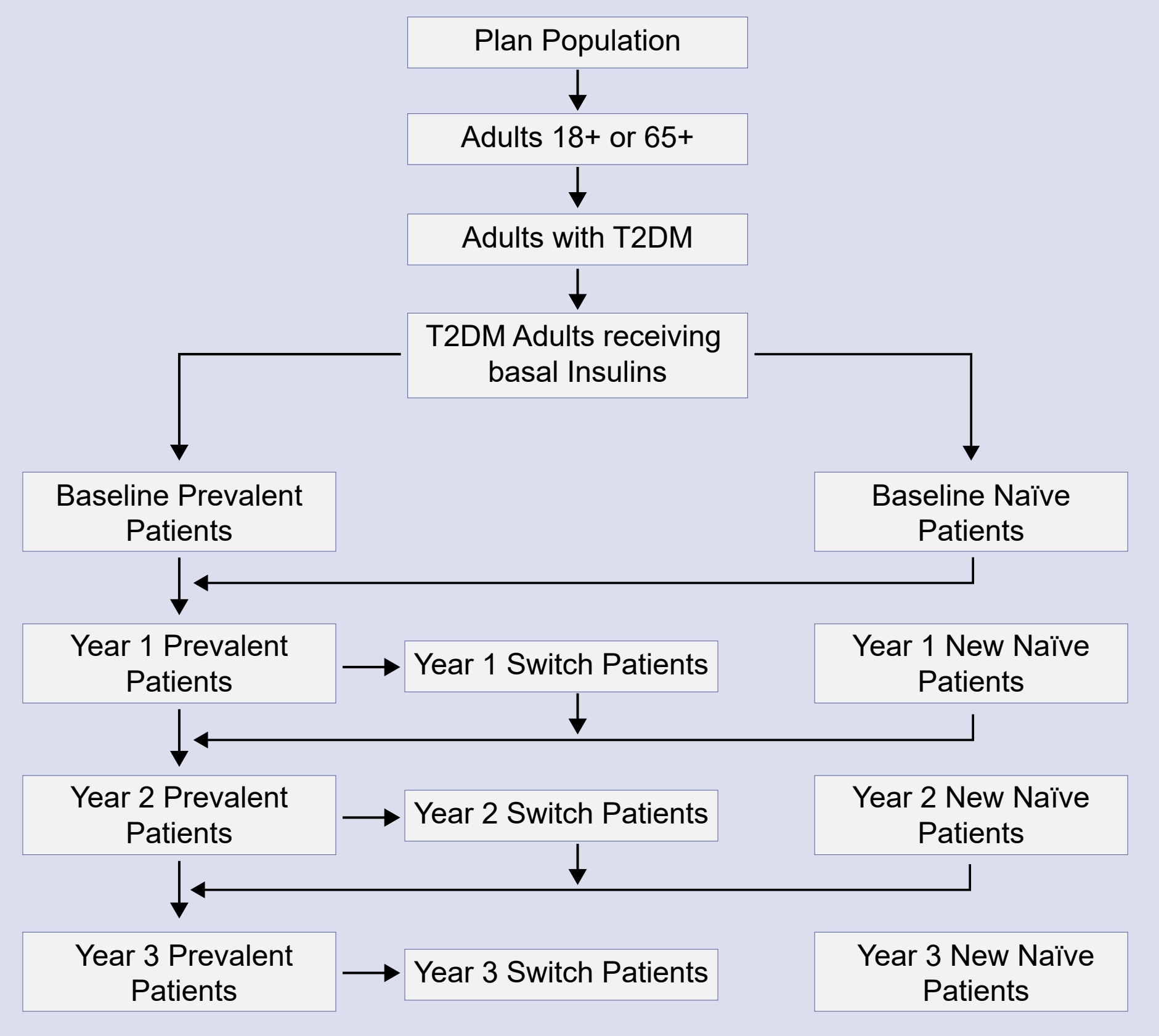


Figure 3. Total budget impact (treatment & all cause costs)

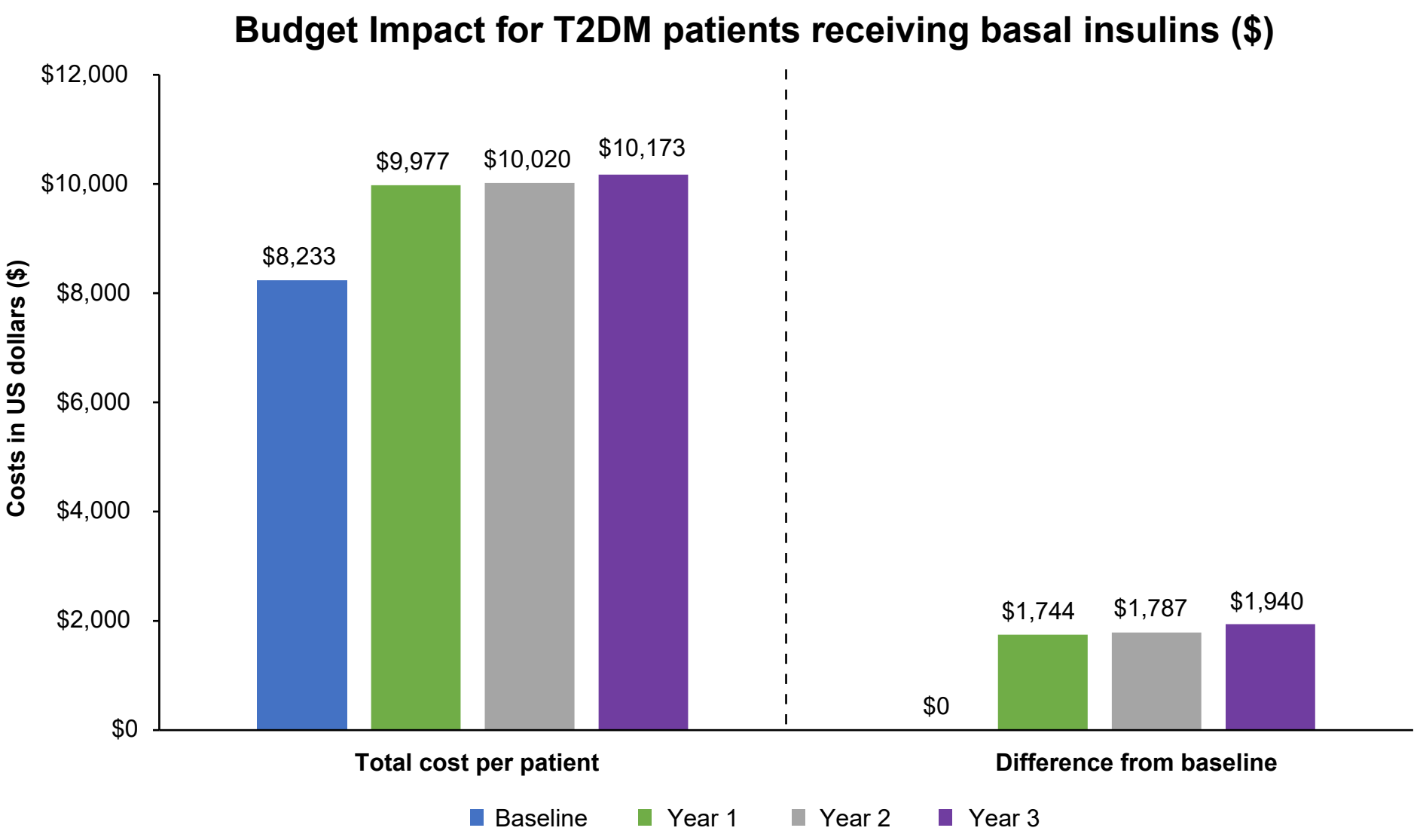


Figure 4. Tornado diagram presenting sensitivity analysis results

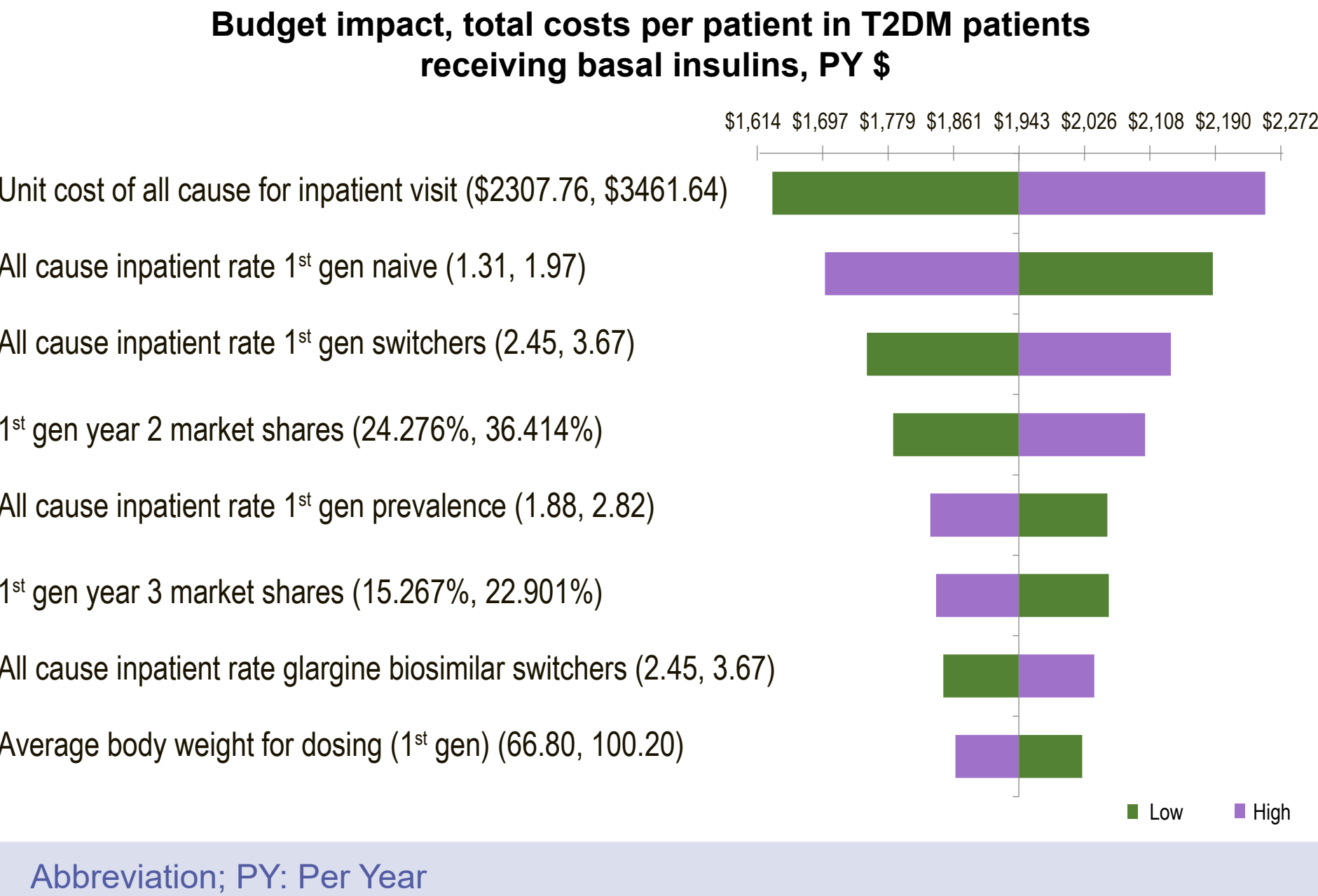


Table 3. Market shares for scenarios

	Scenario 3: 2 nd gen to 1 st gen BIs switch			
Insulin	Y0	Y1	Y2	Y3
2 nd gen BIs	6.69%	5.15%	4.31%	3.07%
1 st gen BIs	80.52%	77.25%	71.81%	61.95%
Glargine biosimilars	0.10%	5.04%	11.54%	22.72%
Insulin degludec	12.69%	12.56%	12.34%	12.26%
Total	100.00%	100.00%	100.00%	100.00%

Abbreviation; BIs: Basal Insulins

Table 4. Scenario results

Scenario number	Scenario	Difference from Baseline, Cumulative, Total Costs per Patient in T2DM patients receiving basal insulins, PY \$
	Base case	\$1,940
1	Modify initial population to 100% prevalent	\$338
2	Net costs vs WAC (impact of treatment costs)	\$2,076
3	Switching market shares for 2 nd gen – 1 st gen BIs	\$839
4	100% market share to 2 nd gen BIs by projected year 3	\$65

Abbreviations; PY: Per Year

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DISCLOSURES

EP and SSSS are employees of Axtria, which received funding from Sanofi for this analysis. CS was employee of Axtria during the conduct of this study. RP, SP, WL, and AR are employees of Sanofi and are stockholders of Sanofi stock.

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RESULTS

Base case analysis

- Results were mainly driven by market share assumptions, lower utilization of HCRU (based on RWE results) with increase in 2nd gen BIs and glargine biosimilars shares, and changes in patient population (naïve/prevalent/switcher) over the projected years
- Switching from 1st gen to 2nd gen BIs, resulted in incremental increased PPPY costs of ~\$1940 and overall cumulative costs of ~\$10,172 by projected year 3 (**Figure 3**)

Base case sensitivity analysis results

- Unit cost for all cause inpatient visits, all cause inpatient rate for 1st gen BIs switchers, all cause inpatient rate for 1st gen BIs prevalent patients, and all cause inpatient rate for glargine biosimilar switchers had the greatest influence on the cost savings PPPY, \$
- Other key variables influencing OWSA results are depicted in **Figure 4**

Scenario results

Other scenarios exploring potential dynamics in the market included the following:

Scenario 1

A 100% prevalent baseline population eliminated the jump in costs between the baseline and projected year 1, whereas the costs for projected year 2 and projected year 3 remained the same.

Scenario 2

Use of net drug costs instead of wholesale acquisition cost (WAC) resulted in a significant decrease in PPPY over the 3-year time horizon.

Scenario 3

Greater uptake of 1st gen over 2nd gen BIs among switchers (**Table 3**) resulted in:

- Lowering of absolute costs compared to the 1st gen to 2nd gen switch scenario due to differing definitions of the HCRU inputs
- A smaller decline in costs for naïve and prevalent populations between projected year 1 and projected year 3 compared to the 1st gen to 2nd gen scenario

Scenario 4

A 100% market share for 2nd gen BIs over projected year 3 leads to incremental cost reduction of 97% as compared to the base case results. Hence, it suggests that eventually as the share of 2nd gen BIs increase over time there will be a minimal increment in cost of ~\$65.

Results for model scenarios are shown in **Table 4** and one-way sensitivity analysis (OWSA) for each scenario is depicted in **Figure 5**.

CONCLUSIONS

- Redistributing the market share from 1st gen to 2nd gen BIs along with increasing market share of glargine biosimilars over the years demonstrated incremental cost reductions over time (Figure 3). Budgetary reductions were achieved by switching patients from 1st gen to 2nd gen BIs
- The market shares highlighted the economic value of increased utilization of 2nd gen BIs driven by the reduction in HCRU
- Findings from this BIM may be used to help guide decision-makers in terms of formulary placement and utilization controls