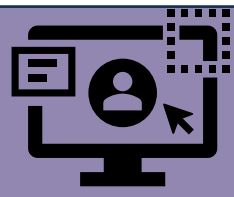


A BUDGET IMPACT ANALYSIS OF AZELASTINE HYDROCHLORIDE/FLUTICASONE PROPIONATE (AZEFLU) NASAL SPRAY SUSPENSION FOR PATIENTS WITH ALLERGIC RHINITIS (AR) IN THE KINGDOM OF SAUDIA ARABIA (KSA)

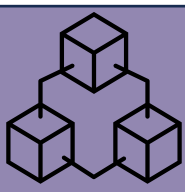
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Background

- The direct medical expenses associated with allergic rhinitis in the USA amount to around \$3.4 billion, with nearly half of this expenditure stemming from prescription medications (46.6%)¹.
- The budget impact analysis included the anticipated costs of introducing a fixed-dose combination nasal spray, AzeFlu, as a potential substitute for the current free combination products.

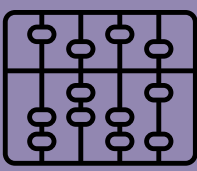


Methodology

- A budget impact model was created using Excel to analyze the financial implications over a 5-year period.
- The model utilized population data (Table 1), and prescription fill data (Table 2) obtained from secondary sources and the regional medical team.
- The budget impact analysis focused on medication costs sourced from the Saudi FDA (Table 2),⁷ without incorporating other expenses related to resource utilization and productivity.
- The market share in the KSA region was used to determine the comparators.
- The population was assumed to remain constant over the 5-year period.

Table 1: Patient Inputs

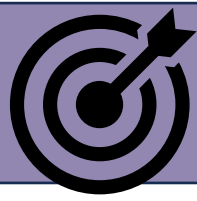
Patient Numbers		
Patient Numbers	Prevalence	National
KSA Population ²	-----	37,358,653
Population over 12 years ³	78.7%	29,404,462
Prevalence (AR) ⁴	21.2%	6,027,024
Moderate to Severe AR ⁵	66%	3,977,836
Patient accessing resources ⁶	38%	1,511,578
Patients with prescription ⁶	69%	1,042,988



Model Analysis

- Patients under 12 years of age were estimated based on the population of Saudi Arabia in the 0-14 age group.
- AzeFlu market share at the beginning was assumed to be 0%, with an expected increase to 1% in Year 1 and 5% by the end of the 5-year period.
- The market share of the free combination of Mometasone and Oral antihistamine is assumed to remain constant. This conservative assumption in the initial scenario reflects the careful approach taken in the model.
- Sensitivity Analysis
 - 35% AR Prevalence
 - 80% patients utilizing health resources
 - 90% patients with a prescription
 - Sensitivity around drug cost and market share not assessed in the model.

- This substitution could alleviate the prescription burden on both patients and the KSA health system.



Model Objective

- Assessing the potential budget impact of introducing azelastine hydrochloride/fluticasone propionate (AzeFlu) nasal spray suspension in government hospitals across Saudi Arabia for individuals with Allergic Rhinitis (AR).

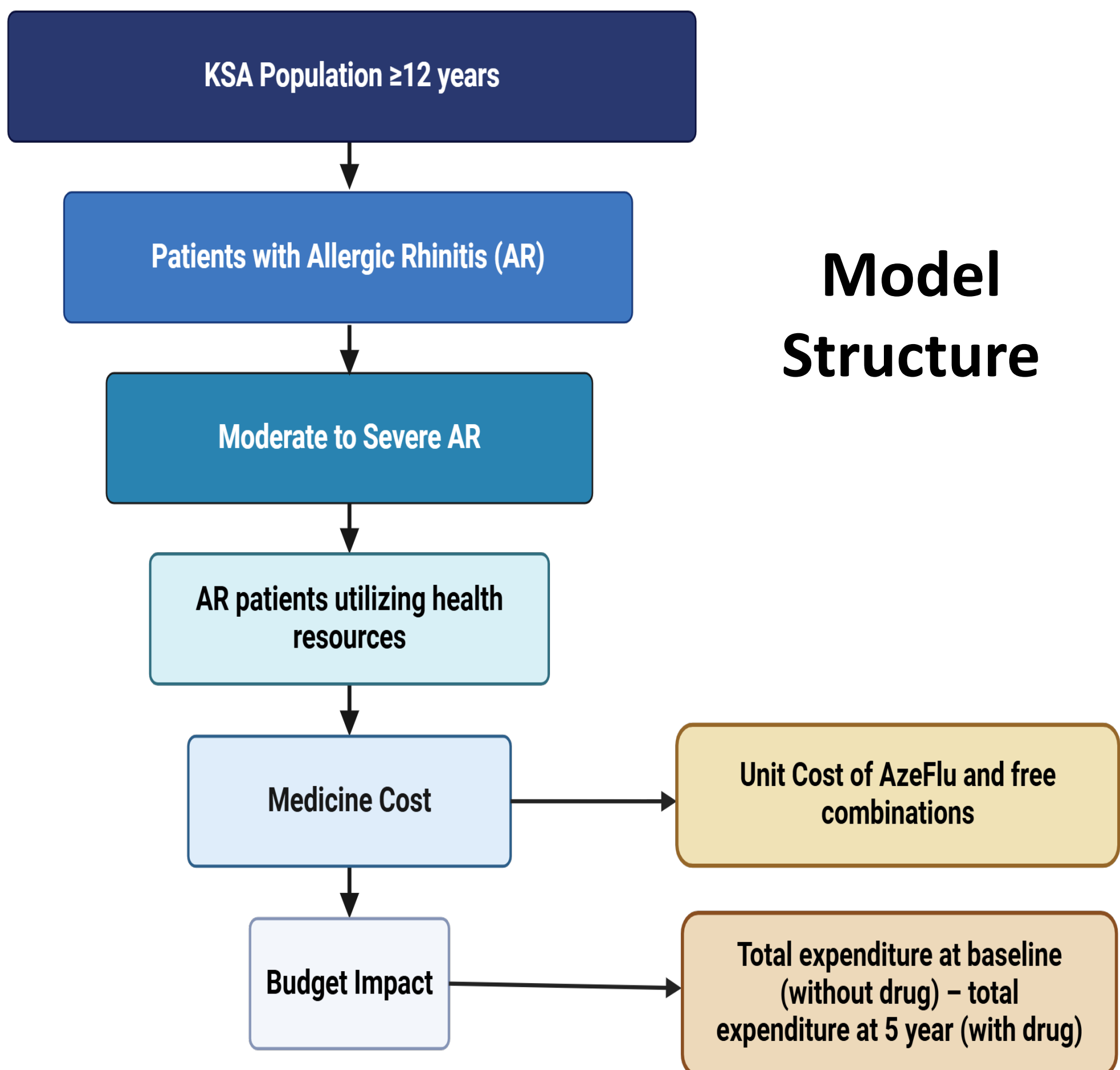
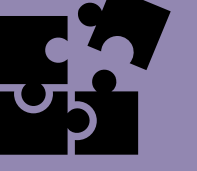


Table 2: Drug Cost (SR)

Drug	Fills ⁶	Drug Unit Cost ⁷	Total Drug Cost
AzeFlu	4	77.20	309
MO	4	73.50	294
FP + OAH	4	50.33	201
Bud + OAH	4	76.28	305
FF + OAH	4	69.93	280
Mom + OAH	4	73.18	293
FP + OAH + ED	4	81.85	327
Bud + OAH + ED	4	107.80	431
FF + OAH + ED	4	101.45	406
Mom + OAH + ED	4	104.70	419



Model Scenarios

Scenario 1

- AzeFlu vs dual therapy free combinations.
- Dual Therapy included: Fluticasone Furoate + OAH (Oral Antihistamine); Mometasone + OAH; Budesonide + OAH.

Scenario 2

- AzeFlu vs triple therapy free combinations.
- Triple Therapy included: Fluticasone Furoate + Oral Antihistamine (OAH) + Eyedrop (ED); Mometasone + OAH + ED; Budesonide + OAH + ED.

Abbreviations:

AR: Allergic Rhinitis; **AzeFlu:** Azelastine – Fluticasone Propionate; **FF:** Fluticasone Furoate; **INS:** Intranasal Spray; **OAH:** Oral anti-histamine; **Mom:** Mometasone; **Bud:** Budesonide; **ED:** Eye drop; **SR:** Saudi Riyal

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Results

AzeFlu introduction in the treatment pathway:

- **Scenario 1 (Figure 1):** Cost neutral to a marginal cost saving of SR 1.1 million at year 5, which is 0.4% of total expenditure at baseline (SR 307,085,268).
- **Scenario 2 (Figure 2):** A cost saving of 7.7 million at year 5, which is 1.8% of total expenditure at baseline (SR 438,510,603).
- **Sensitivity analysis** with AR prevalence and resource utilization showed increased total expenditure but no relative impact on the overall budget.

Figure 1: AzeFlu vs Dual therapy free combinations

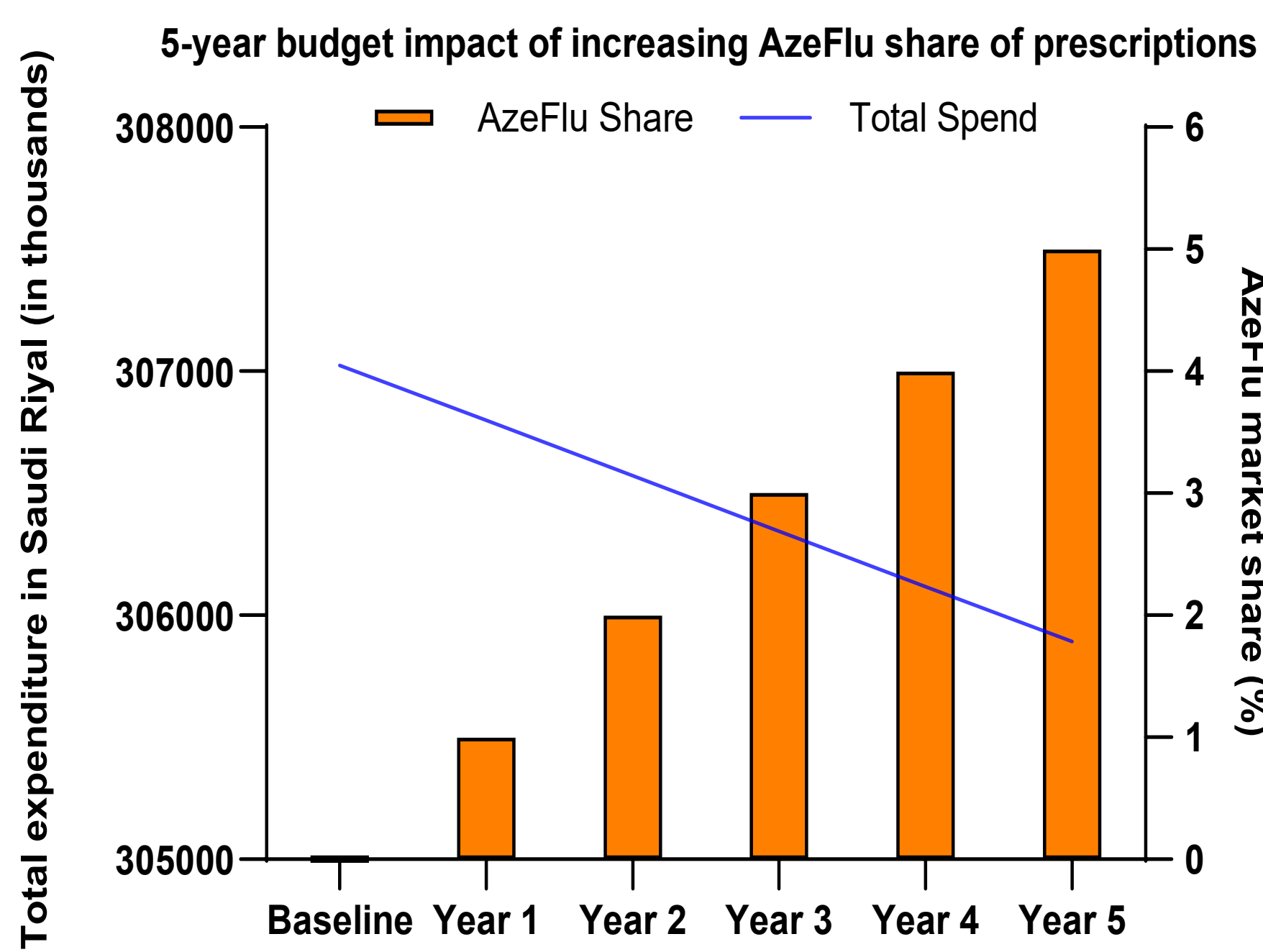
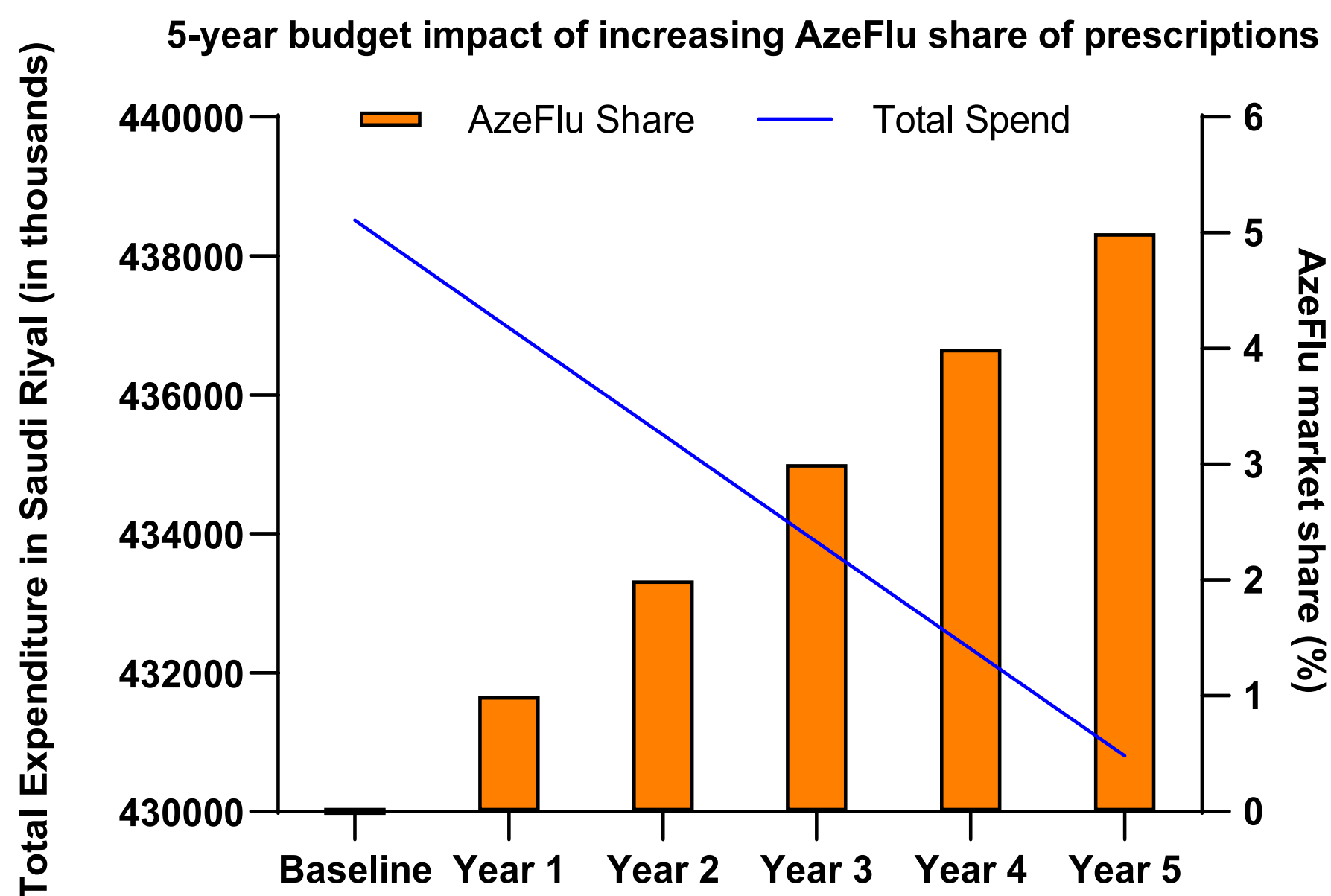


Figure 2: AzeFlu vs Triple therapy free combinations



Conclusions

- The introduction of AzeFlu offers cost-neutral to cost-saving benefits compared to using multiple combination therapies.
- AzeFlu could also result in even greater cost savings with fewer healthcare provider visits. In AR patients with comorbid asthma the cost savings could also be greater.
- The overall reduction in medication burden makes the introduction of AzeFlu an alternative treatment option for allergic rhinitis patients in government hospitals across Saudi Arabia.



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