Budget Impact Analysis of a Triple-Agent Fixed-Dose Combination of 1.2% Clindamycin Phosphate, 0.15% Adapalene, and 3.1% Benzoyl Peroxide Topical Gel for the Treatment of Patients with Moderate-to-Severe Acne Vulgaris in the US

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Background

- Acne vulgaris (AV) is the most common skin condition in the United States (US), affecting up to 8 million Americans annually based on ICD-10 diagnosis codes.¹
- In October 2023, the US FDA approved Cabtreo™, a triple-agent fixed dose combination (FDC) topical gel (clindamycin phosphate 1.2%, benzoyl peroxide (BPO) 3.1%, and adapalene 0.15%) for the treatment of moderate-to-severe AV.²

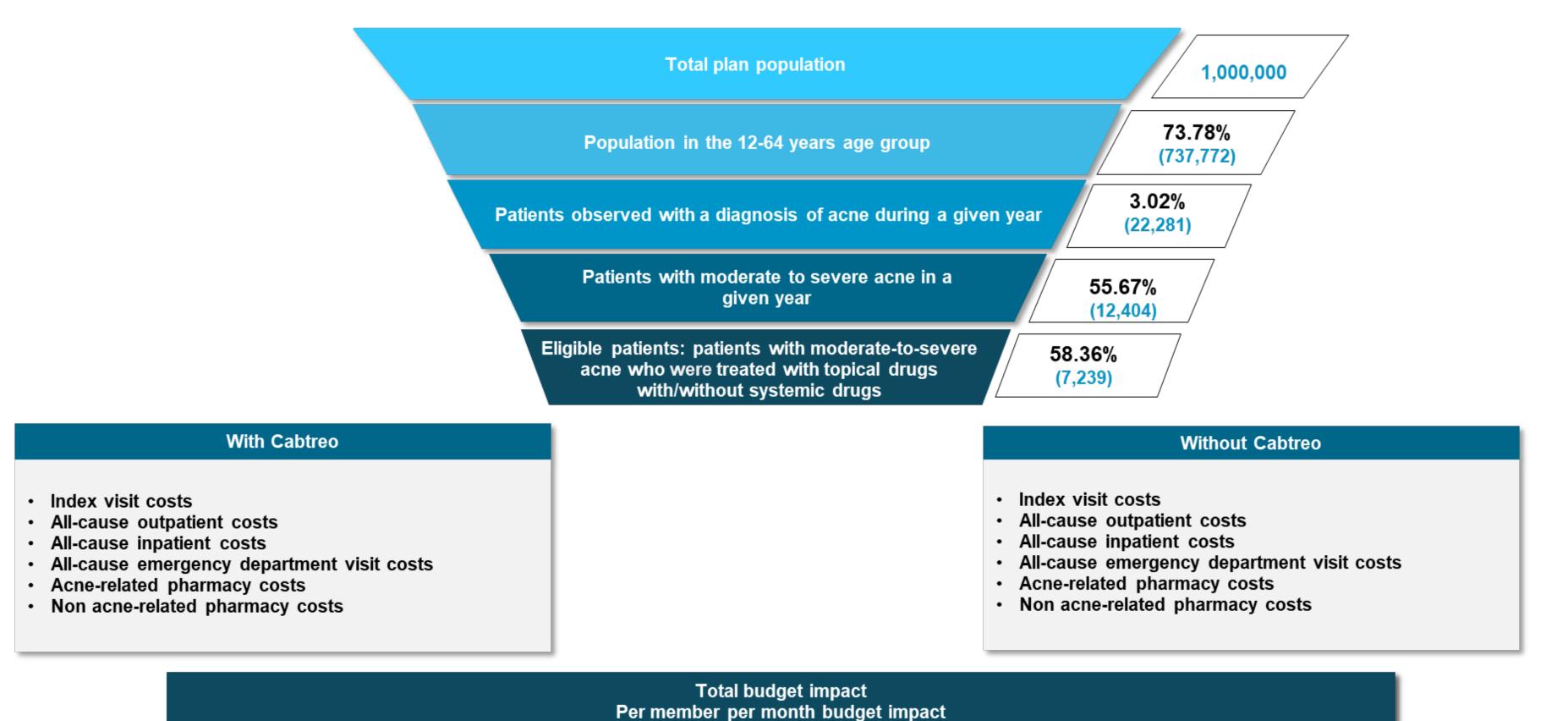
Objective

• This budget impact model (BIM) was developed to estimate the impact of including Cabtreo in the drug formulary as a treatment option for moderate-to-severe AV, on a third-party US commercial payer's budget.

Methods

- A BIM, using an incidence-based approach comparing scenarios with and without Cabtreo, was constructed using Microsoft® Excel.
- Model Overview (Figure 1):
- Population: Patients (12 64 years) with moderate-to-severe AV
- o Payer perspective and eligible population size: US Commercial with a hypothetical 1-million-member population
- Time Horizon: 5 years
- o Treatment scenarios: With Cabtreo vs without Cabtreo.
- O Current treatment mix: Combination of treatments that include oral retinoids, combination of treatments that include spironolactone, combination of treatments that include oral antibiotics, topical retinoid/BPO FDCs, topical antibiotic/retinoid FDCs, topical antibiotic/retinoid monad, topical combinations (fixed dose + fixed dose/monad).
- Model inputs:
 - Epidemiological inputs:
 - Proportion of patients in the 12-64 years age group was obtained from the US Census Bureau Health Insurance Historical Tables.³
 - The 'proportion of patients observed with a diagnosis of acne during a given year' was obtained from the Institute for Health Metrics and Evaluation (IHME) Global Health Data Exchange at the University of Washington.⁴
 - The claims database analysis by Harper et al. 2023 was used to obtain an estimate for the 'proportion of patients with moderate-to-severe acne' and the 'proportion of patients with moderate-to-severe acne who were treated with topical drugs with/without systemic drugs'.¹
- Market share inputs:
- In the absence of data, Cabtreo's market share was based on the historical uptake rate of acne products.
- Market shares for all the other treatments were taken from a claims database analysis.¹
- Cost inputs:
 - A Wholesale Acquisition Cost (WAC) of \$950 per 50g pump of Cabtreo was used in this analysis.⁵
 - Healthcare Resource Utilization (HCRU) costs were obtained from a claims database analysis.¹
- Model outputs: Plan-level and per member per month (PMPM) costs in 2023 US dollars.
- Sensitivity analysis: One-way sensitivity analysis (OWSA) was performed as per ISPOR best practice guidelines.⁶
- The model was developed in accordance with recommendations from the ISPOR Task Force Report: Budget Impact Analysis.⁶

Figure 1: Schematic presentation of budget impact model flow (for a hypothetical 1-million plan)



Results

Figure 2: Total plan level budget impact per million members by year

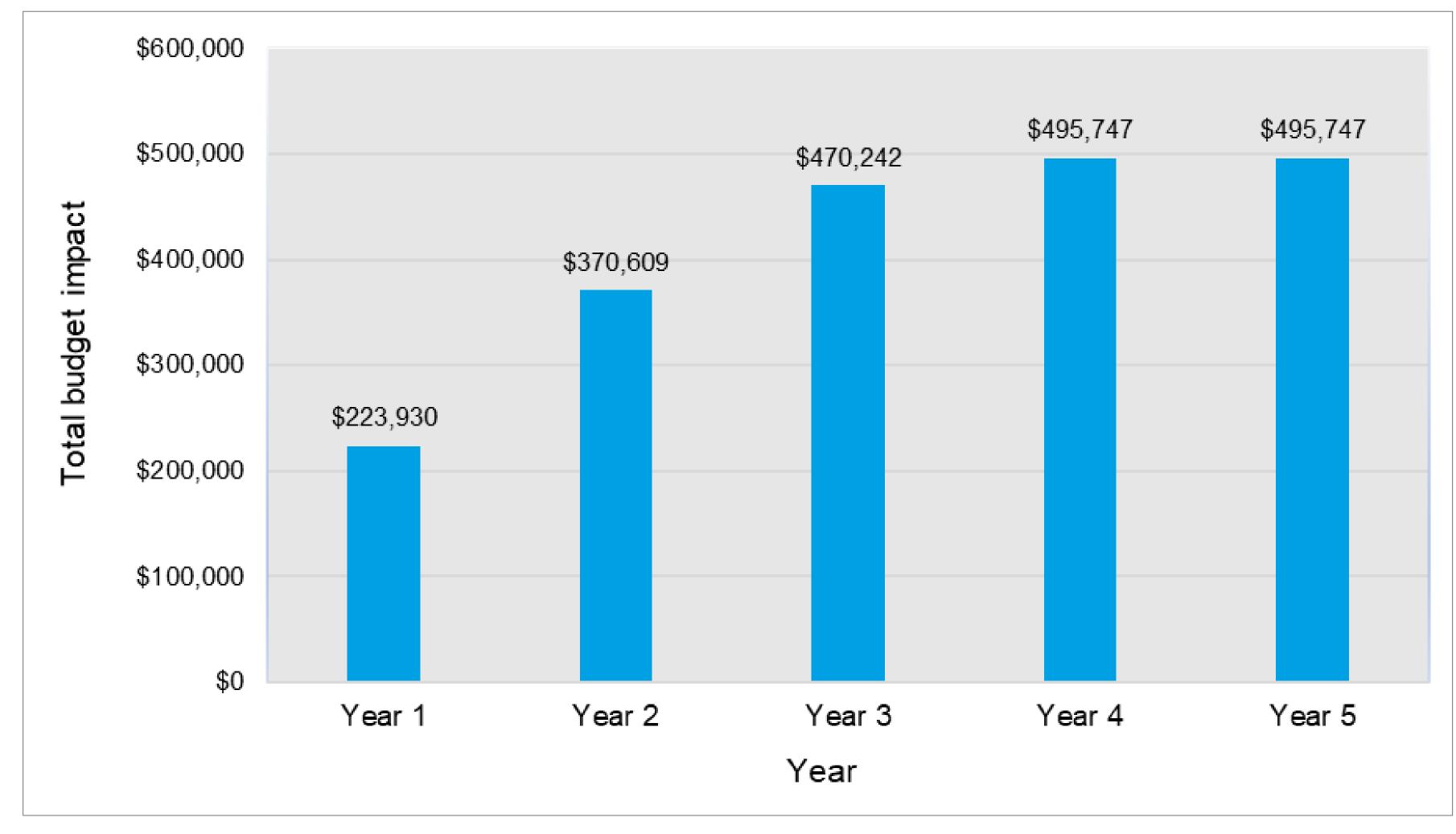


Figure 3: One-way sensitivity analysis for plan level budget impact per million members

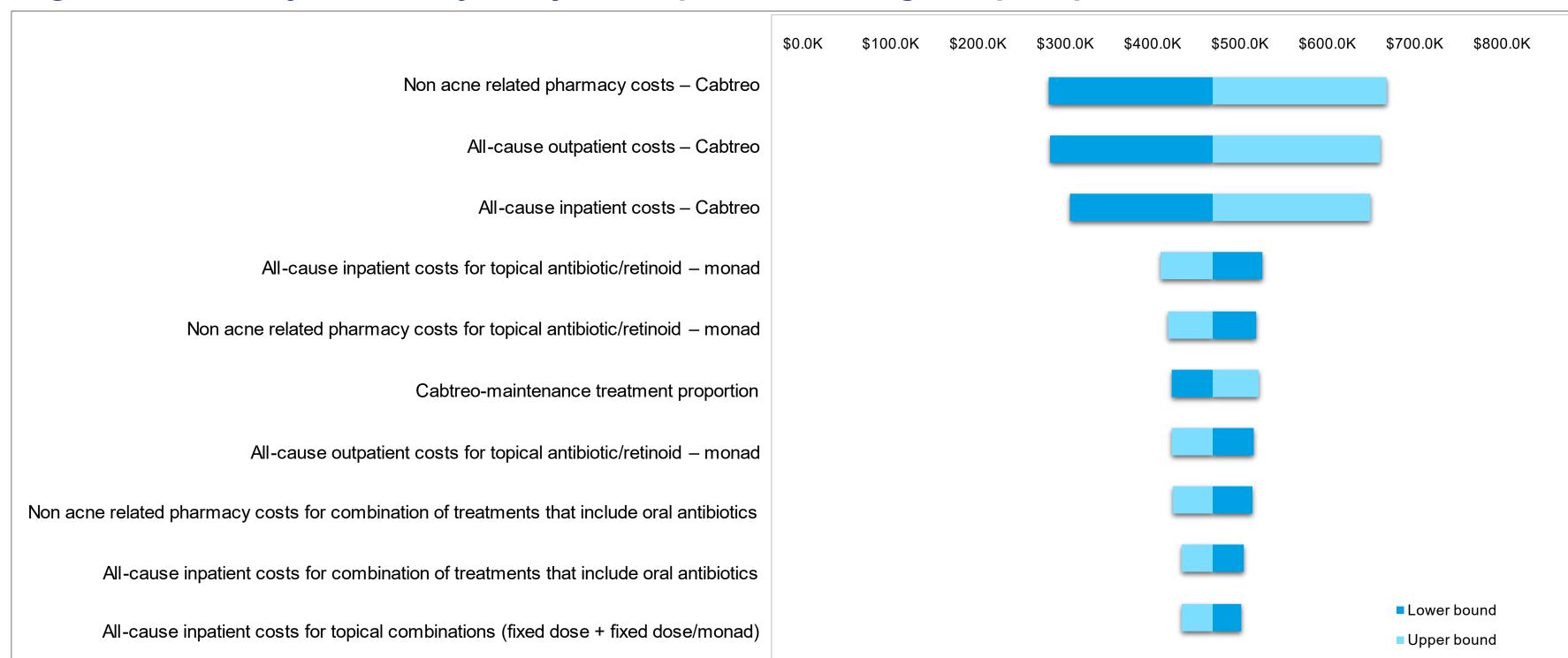
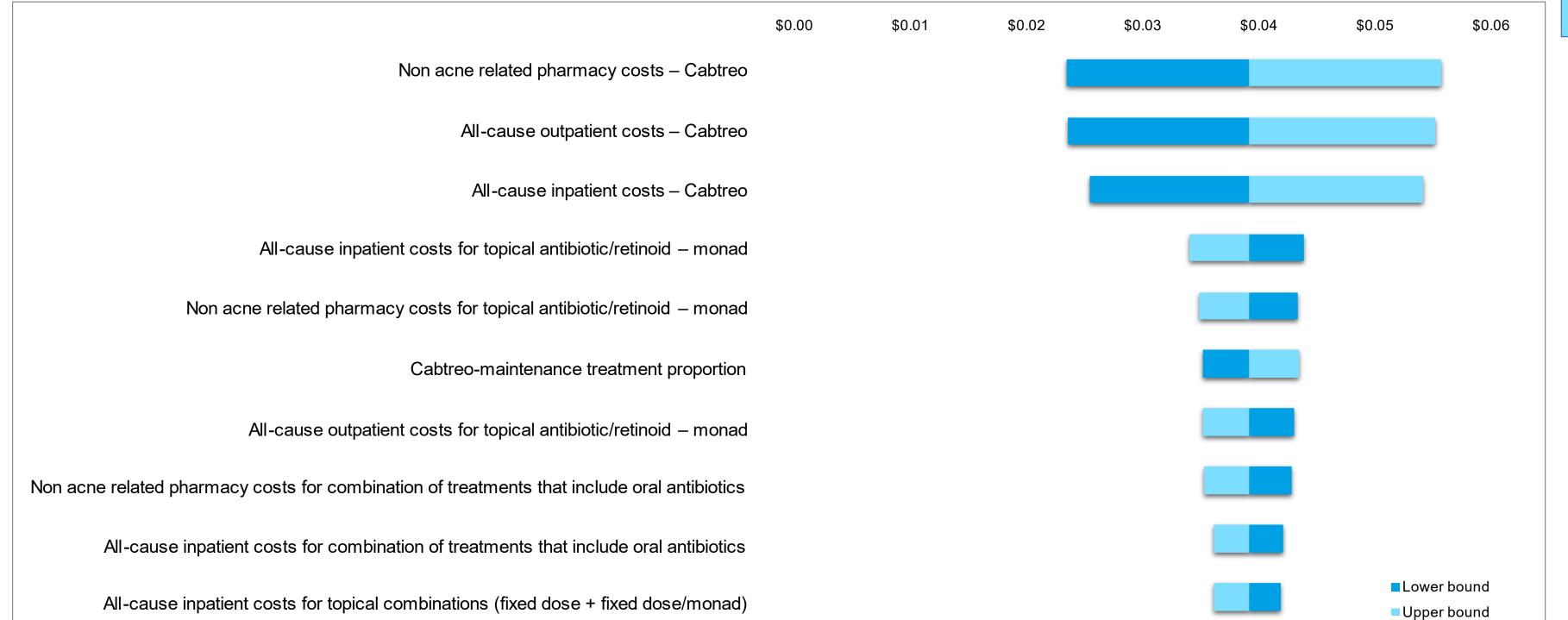


Figure 4: One-way sensitivity analysis for per member per month budget impact



- For a hypothetical population of 1-million Commercial plan members, the total plan level budget impact of Cabtreo for the treatment of moderate-to-severe AV was estimated to be \$495,747 at year 5 (**Figure 2**).
- The PMPM budget impact was estimated to be
 < \$0.05 from Year 1 through Year 5.
- The deterministic OWSA was conducted to assess the impact of the parametric uncertainty on the results of the model. The uncertainty around non-acne-related pharmacy costs emerged as a key value driver (**Figure 3**, **Figure 4**).

Limitations

- With the increased use of Cabtreo as maintenance therapy, the incidence of moderate-to-severe AV may reduce over the years, but this could not be modelled in the absence of data. Due to the absence of data on HCRU costs for Cabtreo, HCRU costs of topical retinoid/BPO – FDCs are used in the analysis as a proxy for HCRU costs of Cabtreo.
- Standardized acne severity assessments (i.e. Evaluator's global acne severity scale (EGSS)) were not available in the claims database analysis, and therefore, moderate-to-severe AV was defined based on prescription fills for treatments typically used for moderate-to-severe AV.
- HCRU and cost inputs obtained from the claims database analysis are subject to common limitations of commercial claims databases, including billing inaccuracies, missing data, and coding errors.

Conclusion

 Results from this budget impact analysis showed that introducing Cabtreo was likely to result in a minimal budget impact on any US commercial health plan's budget.

Disclosure

- This study was funded by Bausch Health US, LLC
- The study sponsor was involved in several aspects of the research, including study design, the interpretation of the data, and the production of the poster.

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