A budget impact analysis of bezlotoxumab for the management of recurrent *Clostridioides difficile* infection in the United States

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OBJECTIVES

- *Clostridioides difficile* infection (CDI) is one of the most frequently reported healthcare-associated infections in the U.S.[1]
- CDI recurrence, as either relapse or reinfection after initial resolution of symptoms following treatment with antibiotics, is common, with approximately 25% of patients experiencing a recurrent infection after completing initial therapy[2,3]
- CDI can result in significant economic burden for both healthcare systems and patients; this can be compounded by the impact of recurrent infections[4]
- The 2021 Infectious Diseases Society of America guidelines recommend the use of bezlotoxumab (BEZ) in addition to standard of care (SoC) antibiotics for patients who have a CDI episode and at least one risk factor for recurrence[5]
  - Risk factors include a recurrent CDI (rCDI) episode within the last 6 months, age ≥65 years, immunocompromised host, and severe CDI on presentation
- The demonstrated efficacy of BEZ to reduce rCDI vs. placebo when combined with SoC suggests that it may also reduce healthcare costs
- The objective of this study was to estimate the budget impact of the use of BEZ + SoC vs. SoC alone from a hospital perspective in the U.S.

METHODS

Budget impact model

- A decision analytic model was developed considering treatment of the index rCDI episode and subsequent recurrences (a maximum of two) over a 1-year period
- The analysis included patients who had at least one risk factor for rCDI
- Two scenarios were compared: one with BEZ + SoC and one with SoC alone
  - The budget impact was calculated as the difference in revenue between scenarios (**Figure 1**)

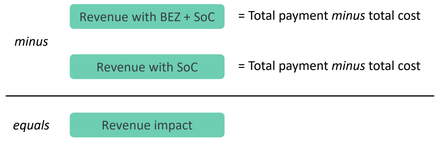

Figure 1. Budget impact model structure

- The analysis included costs of and payments for medications and the cost of managing rCDI, as well as the proportion of BEZ utilization across management settings (assuming 50% inpatient and 50% outpatient)
  - Drug revenue was calculated as the difference between the total cost and total payment received
  - Cost included the cost of treating rCDI episodes and the acquisition cost of BEZ (when considered)
  - Payment included the reimbursement rate for managing rCDI and the reimbursement for BEZ
- Costs were expressed in 2021/2022 U.S. dollars
- One-way sensitivity analyses were performed on key parameters

Parameters

- The analysis used a time horizon of 1 year, with 10,000 patients admitted per year and 1.4% of patients admitted for CDI[6]
- Initial BEZ uptake was assumed to be 100%
- Based on BEZ clinical trial data, the proportion of patients with at least one risk factor was 75.6%[7]
  - The rate of first recurrence was 21.2%[7], and the rate of subsequent recurrence was 45.0%[8,9]
  - The readmission rate for rCDI was 85.0%[10]
- The cost of BEZ was $3,800 per vial
- The cost of rCDI was estimated at $24,604, and payments were estimated at $14,212 based on a retrospective database study[11] and inflated to 2021/2022 dollars[12]

RESULTS

- Among 10,000 hypothetical hospitalizations, treatment of at-risk patients with BEZ + SoC instead of SoC alone in the base case analysis was estimated to result in a potential savings of $53,361 at the hospital level, $497 per treated rCDI patient, and $5.34 per admitted patient (**Figure 2**)
- The additional cost of BEZ was offset by the lower rCDI rate in those treated with BEZ

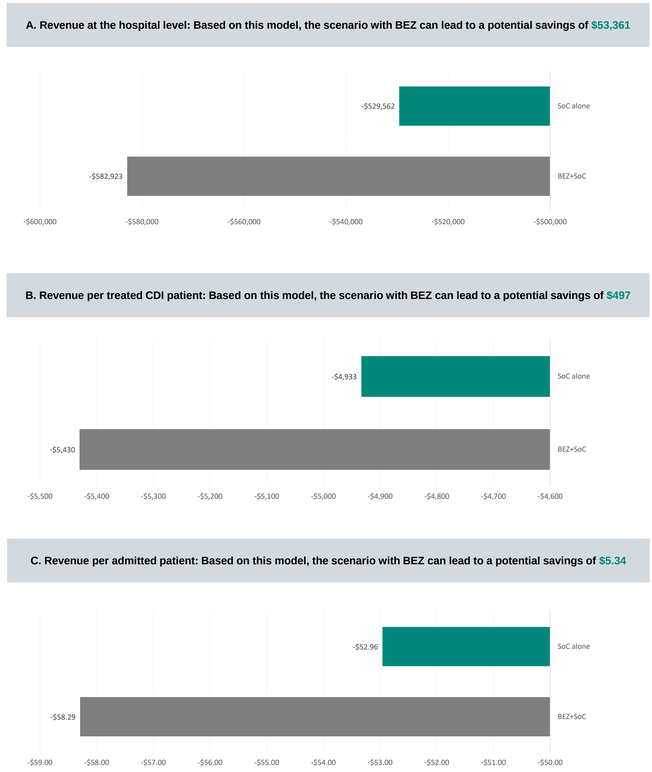

Figure 2. Budget impact of BEZ for patients with at least one CDI risk factor

- Sensitivity analyses demonstrated the robustness of results, with the use of BEZ resulting in savings in most scenarios tested (**Figure 3**)

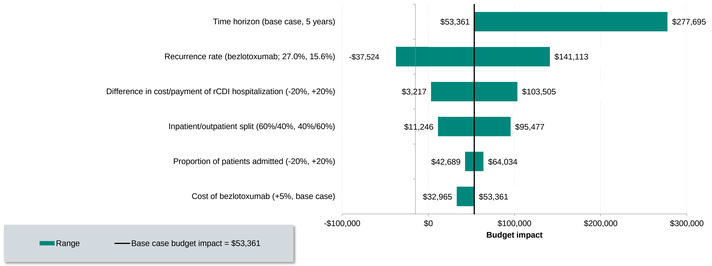

Figure 3. Sensitivity analysis of budget impact of BEZ at the hospital level for patients with at least one CDI risk factor

LIMITATIONS

- The construction of the budget impact model and the results derived thereof required disparate information, expert opinion, and several assumptions
- The data reflected in the model were an estimate of potential budgetary impact; actual financial results may differ based on a variety of factors
- This model is not relevant for patients who are not at high risk of rCDI

CONCLUSIONS

- For patients with CDI who are at risk of recurrence, the addition of BEZ to SoC treatment can result in cost savings at the hospital level, per treated CDI patient, and per admitted patient
- Broader benefits of BEZ + SoC should be considered by healthcare stakeholders and policy makers when making decisions about formulary inclusion and adoption

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