Cost Effectiveness Model on Four Preventive Treatments for Clostridioides Difficile Infection Recurrence from a US Payer Perspective

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Background

- Clostridium difficile infection (CDI) is a common nosocomial infection (2019 CDC report: 121.2 cases per 100,000 persons)
- 20 - 35% patients will experience a recurrence
- Preventive treatments: bezlotoxumab (a monoclonal antibody) and three fecal microbiome transplantation (FMT) products: RBX-2660; SER-109; and CP101 (not FDA approved)
- Total annual CDI-attributable cost in the US is estimated US$6.3 (Range: $1.9–$7.0) billion

Objective

To determine the cost-effectiveness of CDI treatments to prevent recurrence of CDI (rCDI)

Methods

Design: Decision-analytic Markov Model

Comparators: bezlotoxumab, RBX-2660; SER-109; and CP101

Perspective: US Healthcare Payer

Time horizon: 1-year (2 months cycles)

Population: Patients with a previous resolved CDI **Age:** 64 years old

Sex: 50% Male, 50% Female

Health states: well (no recurrence of CDI), CDI recurrence, and death

Probability of efficacy, failure (recurrence) and death Risk of adverse events (AE) and severe AE

Dis-utility values for: post-treatment infection, recurrence, AE, and hospitalization

Clinical trials for the various products were used to provide the model inputs.

Willingness-to-pay (WTP) threshold: $150,000 per QALY

End points: costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs)

Probabilistic and deterministic sensitivity analyses were conducted

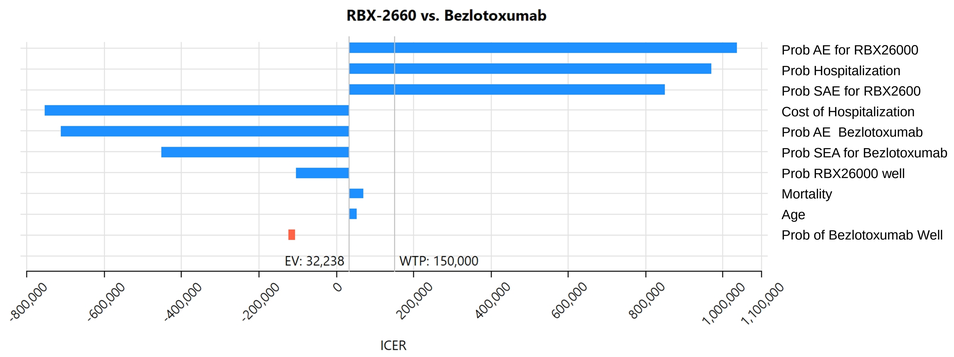
Results

- RBX-2660 was associated with the lowest costs over the time horizon
- CP-101 was completely dominated by RBX-2660
- CDI recurrence and medication AE rates were the primary drivers of the model
- Bezlotoxumab was the most cost-effect option

Table 1. Model Inputs

CDI Treatment	Effectiveness (Probability of no rCDI)	Cost ($)	Probability of Adverse Event (AE)	Probability of Serious Adverse Event (SAE)
RBX-2660	0.712	9,000	0.556	0.056
SER-109	0.876	17,500	0.933	0.070
CP101	0.745	17,500	0.923	0.154
Bezlotoxumab	0.835	3,530.93	0.617	0.198

Figure 3. Deterministic Sensitivity Analysis 2-way Tornado Diagram



Prob: probability; AE: Adverse Event; SAE: severe adverse event;

Table 2. Cost, Effectiveness, and Incremental Cost-Effectiveness Ratio, Base Case

CDI Treatment	Cost	Incremental Cost	Effectiveness (QALY)	Incremental Effectiveness	ICER ($/QALY)
RBX-2660	$19,348	N/A	0.921	N/A	N/A
SER-109	$25,310	$5,720	0.950	0.021	$267,015
CP101	$37,599	$12,288	0.912	-0.038	-$324,855
Bezlotoxumab	$19,591	$243	0.928	0.008	$32,238

Figure 1. Incremental Cost-Effectiveness Scatterplot of RBX-2660 vs Bezlotoxumab

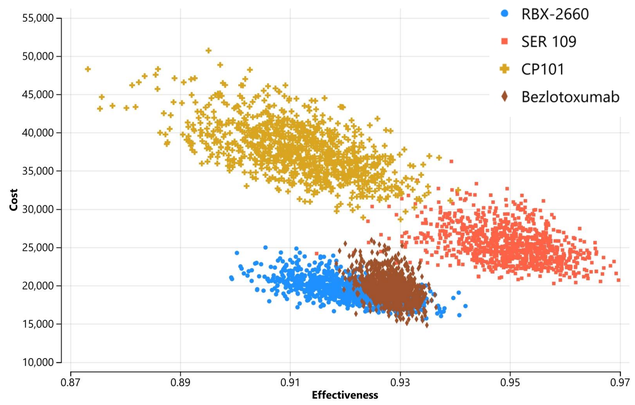
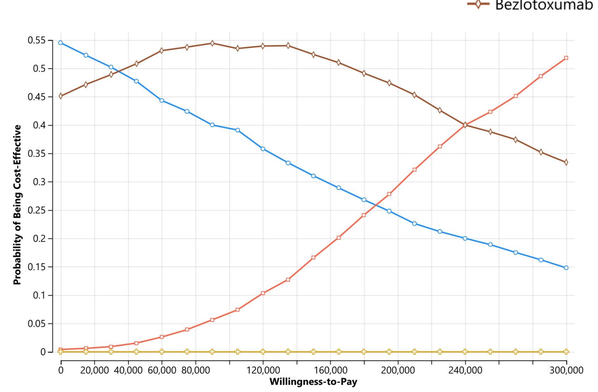


Figure 2. Cost-effectiveness Acceptability Curve



Conclusion

Compared to other preventive treatments for the recurrence of CDI, RBX-2660 had the lowest cost but bezlotoxumab had the highest probability of being cost-effective at the $150,000 WTP threshold