TECHNICAL APPENDIX

Additional Model Structure Details

The 15-day cycle length was used in the model as a conservative estimate to adequately cover both fidaxomicin and bezlotoxumab populations and to maintain consistency when modeling the population, as the recommended course of antibiotic therapies, including vancomycin and fidaxomicin, is usually 10-14 days [1]. We limited this to the initial 6 months since recurrent CDI episodes attributed to the same infectious strains rarely occur beyond 6 months after the initial episode [2]. Lifetime horizon was used to incorporate the permanent impact of colectomy.

Although different definitions for initial and sustained clinical cure were used in the clinical trials, all trials used decreased stool frequency and/or improved stool consistency at the end of the first treatment courses as an indicator of initial clinical cure, and defined patients without recurrence during the follow-up period as having sustained clinical cure [3-6]. Therefore, although the actual dates of assessment are slightly different among trials, it is assumed that these definitions were sufficiently consistent for comparing their outcomes due to data limitations. The sustained cure rates estimated on Day 90 in Guery et al were used as global sustained cure rates to capture the most patients [7]. Patients in clinical failure were assumed to take second-line vancomycin taper therapy, an alternative vancomycin therapy commonly used when other therapies fail [2]. Patients with 1st and 2nd recurrent CDI episodes were again treated with their initially assigned therapy in the initial episode, and were assumed to receive vancomycin taper therapy once they experienced the 3rd recurrent episode, regardless of previous treatment success and failure. Due to lack of data and

for model clarity, we assumed all patients had a maximum of 3 recurrent CDI episodes [8]. During the initial 6 months (biweekly cycles), the probability of progressing to death was explained by a combination of background mortality and 6-month CDI-attributable mortality, while only background mortality was applied after the model progressed into annual cycles (beyond 6 months) [9,10]. Post-colectomy, we included colectomy-specific mortality in addition to background and CDI-attributable mortality [11].

There were some key differences between our model and that of Prabhu et al. First, in Prabhu et al, mild/moderate CDI and severe CDI were assumed to experience different clinical cure rates, and only patients with severe CDI could potentially receive colectomy [2]. While it was confirmed by clinical guideline recommendations that colectomy should be performed only on severely ill patients with fulminant CDI when surgical management was necessary [12], all CDI patients were assumed to go through the same pathway in our model. This was mainly due to the data limitation in bezlotoxumab trial, where clinical cure rates and recurrence rates were not reported specifically in mild/moderate CDI and severe CDI subgroups [1]. Additionally, the fundamental definitions of clinically severe CDI used in randomized trials were different, and the severe CDI population was thus still heterogeneous even if we modeled it separately from mild/moderate CDI population [3-6]. As a result, we decided to model the same health states for all CDI patients. As an alternative, we incorporated the impact of severe CDI by adjusting disease utility according to severe CDI proportion in population.

Furthermore, our model did not include post clinical failure state like Prabhu et al did. Prabhu et al assumed that patients with clinical failure, defined as no respond after one course of treatment, may be further treated in post clinical failure

state and would eventually be cured if they did not progress to death [2]. However, our clinicians suggested that clinical failure was usually due to slow response of patients, and dosage boost were often administered in this case. Based on clinical observations, clinicians estimated that all patients with the correct diagnosis and consistent use of vancomycin will respond within 2-4 weeks. We therefore excluded the post clinical failure state in our model and assumed that all patients with clinical failure would get vancomycin taper for 4 weeks as dosage boost, regardless of which treatment they used previously, and all patients would move to clinical cure after 2-4 weeks if they did not progress to death during this period.

Fecal microbiota transplantation (FMT) is an emerging treatment for recurrent CDI, and articles also suggest that FMT is the preferred and the most cost-saving option [12]. However, due to limited data on prices, clinical rates and utility values of varying methods of FMT so far, modeling FMT treatment would be very difficult and would require a very large number of assumptions. As a result, we decided that incorporating FMT based on current literature is not ideal and FMT was excluded from the model.

Although metronidazole was also sometime used as standard therapy for CDI, clinical practice guidelines for CDI always recommend vancomycin over metronidazole for adult CDI patients as long as the access to vancomycin was not limited [1]. Previous randomized trial showed that oral vancomycin was superior to metronidazole with regard to initial and sustained clinical response, and metronidazole was also not recommended to be used for more than one course because of the potential for cumulative neurotoxicity [1]. Therefore, we also excluded metronidazole from the analysis and used oral vancomycin as the only standard therapy.

The original assumption of the model was 1) biweekly cycle for the initial 6 months and 2) annual cycle for the remaining life. However, due to the fact that only post-colectomy, sustained cure and death states had cycle length of one year, and the fact that some proportion of the patients remain in 3rd recurrence or clinical cure from that episode by the end of the 6th month, pseudo-biweekly cycles were used to mimic annual cycles in model calculation until all patients enter long term stages. In the pseudo-biweekly cycle part, the original annual probabilities were transferred into biweekly probabilities using DEALE method [13,14]. Costs and QALYs were also deducted to meet the length of each cycle.

Additional Input Parameter Details

The data for standard fidaxomicin and vancomycin was calculated from the weighted average of reported numbers from Cornely et al and Louie et al [4,5]. The specific probabilities of sustained clinical cure for initial episodes and recurrent episodes with bezlotoxumab plus vancomycin were assumed to be the same as vancomycin because of data limitations in Wilcox et al and based on the assumption that the effectiveness of bezlotoxumab plus vancomycin was at minimum equivalent to that of vancomycin [3]. Similarly, the probabilities of sustained clinical cure with extended-pulsed fidaxomicin were assumed to be the same as standard fidaxomicin due to data limitations in Guery et al [6].

There are no clinical trials comparing fidaxomicin against bezlotoxumab directly. However, since fidaxomicin trials compared fidaxomicin against vancomycin, and bezlotoxumab trial also compared bezlotoxumab against standard therapy which included vancomycin, we did an adjustment to data of Wilcox et al to mimic the head-to-head comparison [3-5]. Assuming that the effect of standard therapy in Wilcox et al equals the effect of vancomycin, and that the vancomycin

efficacy was constant, the calculation used following equation to obtain the adjusted values of bezlotoxumab probabilities: (Adjusted Bezlotoxumab Probabilities = Original Bezlotoxumab Probabilities / Original Vancomycin Probabilities in Bezlotoxumab Trial * Original Vancomycin Probabilities in Fidaxomicin Trials). Similar adjustment of Guery et al data was also conducted using the following equation: (Adjusted Extended Fidaxomicin Probabilities = Original Extended Fidaxomicin Probabilities / Original Vancomycin Probabilities in Extended Fidaxomicin Trial * Original Vancomycin Probabilities in Standard Fidaxomicin Trials) [6].

Sustained clinical cure rates from recurrent episodes were reported in randomized trials without specifying numbers of patients' recurrences [3-6]. In order to calculate specific sustained clinical cure rates from 1^{st}, 2^{nd} and 3^{rd} recurrent episodes, we assumed that the reported value in literature was a sum up of all sub probabilities: (sustained cure from 1^{st} recurrence + sustained cure from 2^{nd} recurrence + sustained cure from 3^{rd} recurrence = reported value of sustained clinical cure from recurrences in literature). Additionally, as clinicians suggested, we further assumed that (sustained cure from a^{th} recurrence = sustained cure from $[a-1]^{th}$ episode * percentage increase of recurrence rate from $[a-1]^{th}$ to a^{th}, a=2, 3). The sustained clinical cure rates from 1^{st}, 2^{nd} and 3^{rd} recurrent episodes were then calculated by solving the two equations.

Indirect costs in this model came from time loss attributable to CDI symptoms and its treatments. Our clinicians first estimated that a typical outpatient visit for CDI would take a patient 2 hours. Moreover, the time loss of inpatient CDI was calculated from one-third of attributable hospitalization length reported in Zhang et al, assuming that patients only utilize one-third of their total time to work [15]. The general time

loss attributable to CDI was calculated by adjusting inpatient and outpatient time loss with population proportion of inpatient CDI cases. Finally, according to the administration guidelines, we assumed that bezlotoxumab be administered through a 60-minute intravenous infusion [16]. All time loss was then multiplied by civilian compensation rate to gain the final indirect costs.

The utility measurement of CDI was not well established among literature. Consequently, the utility values used by previous cost-effectiveness analyses were considerably different, and thus we made reasonable adjustments to the derived utility values. First, the baseline utility from Bartsch et al was adjusted by proportion of patients who aged 65+ years [17]. Second, we took the disutility of CDI states from Prabhu et al, adjusted by proportion of severe CDI, and then multiplied the disutility by the baseline utility to calculate the final value of diseased utility [2]. As colectomy was performed on severe CDI patients only and took less than one week to complete, we further assumed the utility of colectomy was the same as that of severe disease. The utility of colectomy was calculated using the disutility of severe CDI and not adjusted by any proportion.

Finally, following the assumption in Lam et al, the utility of post-colectomy was produced based on the same assumption in Hayes et al and the EQ-5D-5L utility value of United States population due to a lack of relative data [18-20]. Hayes et al used the assumed values according to EuroQol Group's EQ-5D-3L health state classification system to represent utilities of patients in post-colectomy state [19]. EQ-5D-3L defines utilities in five dimensions and three possible levels of experience: 1, no problems; 2, moderate problems; and 3, extreme problems. Hayes et al assumed that post-colectomy patients were at level 2 for all five dimensions and produced the associated utility value [19]. We applied similar assumption on EQ-5D-5L, in which

utilities were defined in five possible levels of experience instead of three: 1, no problems; 2, slight problems; 3, moderate problems; 4, severe problems; and 5, extreme problems. We assumed that post-colectomy patients in our model were at level 3 for all dimensions and derived the associated United States specific value from Pickard et al [20].

Description	Base Value	Range			Distribution	Reference
Sustained clinical cure, 1st Recurrence, VAN	0.254	0.203	-	0.305	Beta	[4,5]
Sustained clinical cure, 1st Recurrence, FDX	0.384	0.307	-	0.461	Beta	[4,5]
Sustained clinical cure, 1st Recurrence, BEZ	0.254	0.203	-	0.305	Beta	N/A *
Sustained clinical cure, 1st Recurrence, EPFX	0.384	0.307	-	0.461	Beta	N/A **
Sustained clinical cure, 2nd Recurrence, VAN	0.193	0.155	-	0.232	Beta	[4,5]
Sustained clinical cure, 2nd Recurrence, FDX	0.245	0.196	-	0.294	Beta	[4,5]
Sustained clinical cure, 2nd Recurrence, BEZ	0.193	0.155	-	0.232	Beta	N/A *
Sustained clinical cure, 2nd Recurrence, EPFX	0.245	0.196	-	0.294	Beta	N/A **
Sustained clinical cure, 3rd Recurrence, VAN	0.140	0.112	-	0.168	Beta	[4,5]
Sustained clinical cure, 3rd Recurrence, FDX	0.110	0.088	-	0.132	Beta	[4,5]
Sustained clinical cure, 3rd Recurrence, BEZ	0.140	0.112	-	0.168	Beta	N/A *
Sustained clinical cure, 3rd Recurrence, EPFX	0.110	0.088	-	0.132	Beta	N/A **
Background mortality, year 3	0.012	0.010	-	0.015	Beta	
Background mortality, year 4	0.013	0.011	-	0.016	Beta	
Background mortality, year 5	0.014	0.012	-	0.017	Beta	
Background mortality, year 6	0.016	0.013	-	0.019	Beta	
Background mortality, year 7	0.017	0.014	-	0.020	Beta	
Background mortality, year 8	0.018	0.015	-	0.022	Beta	
Background mortality, year 9	0.020	0.016	-	0.024	Beta	
Background mortality, year 10	0.022	0.018	-	0.027	Beta	
Background mortality, year 11	0.024	0.019	-	0.029	Beta	[21]
Background mortality, year 12	0.027	0.021	-	0.032	Beta	
Background mortality, year 13	0.029	0.024	-	0.035	Beta	
Background mortality, year 14	0.033	0.026	-	0.039	Beta	
Background mortality, year 15	0.036	0.029	-	0.043	Beta	
Background mortality, year 16	0.040	0.032	-	0.048	Beta	
Background mortality, year 17	0.044	0.035	-	0.053	Beta	
Background mortality, year 18	0.049	0.039	-	0.059	Beta	
Background mortality, year 19	0.055	0.044	-	0.066	Beta	

Background mortality, year 20	0.061	0.049	-	0.073	Beta
Background mortality, year 21	0.068	0.054	-	0.082	Beta
Background mortality, year 22	0.076	0.060	-	0.091	Beta
Background mortality, year 23	0.084	0.067	-	0.101	Beta
Background mortality, year 24	0.094	0.075	-	0.113	Beta
Background mortality, year 25	0.105	0.084	-	0.126	Beta
Background mortality, year 26	0.117	0.094	-	0.140	Beta
Background mortality, year 27	0.131	0.105	-	0.157	Beta
Background mortality, year 28	0.146	0.117	-	0.175	Beta
Background mortality, year 29	0.162	0.130	-	0.194	Beta
Background mortality, year 30	0.179	0.143	-	0.215	Beta
Background mortality, year 31	0.198	0.158	-	0.238	Beta
Background mortality, year 32	0.218	0.174	-	0.261	Beta
Background mortality, year 33	0.238	0.190	-	0.285	Beta
Background mortality, year 34	0.257	0.206	-	0.309	Beta
Background mortality, year 35	0.276	0.221	-	0.331	Beta
Background mortality, year 36	0.294	0.235	-	0.352	Beta
Background mortality, year 37	0.310	0.248	-	0.372	Beta
Background mortality, year 38	0.327	0.262	-	0.393	Beta
Background mortality, year 39	0.345	0.276	-	0.414	Beta
Background mortality, year 40	0.364	0.292	-	0.437	Beta
Background mortality, year 41	0.385	0.308	-	0.462	Beta
Background mortality, year 42	0.406	0.325	-	0.487	Beta
Background mortality, year 43	0.429	0.343	-	0.514	Beta
Background mortality, year 44	0.452	0.362	-	0.543	Beta
Background mortality, year 45	0.478	0.382	-	0.573	Beta

Abbreviations: VAN, vancomycin; FDX, standard fidaxomicin; BEZ, bezlotoxumab plus vancomycin; EPFX, extended-pulsed fidaxomicin.

* Assumed to be the same as vancomycin;

** Assumed to be the same as standard fidaxomicin.

APPENDIX TABLE 1: Additional Clinical Probability Inputs

APPENDIX REFERENCES

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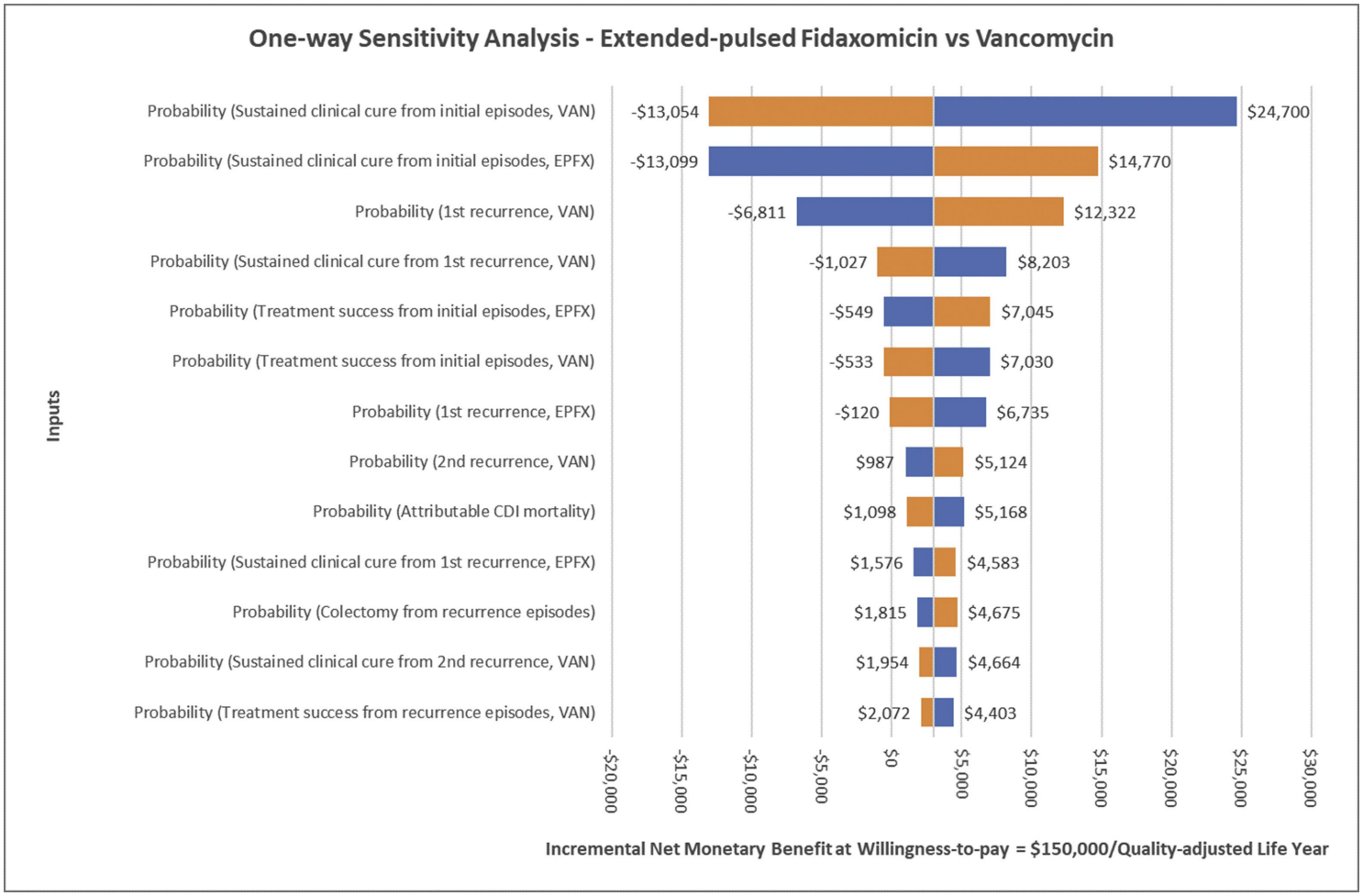
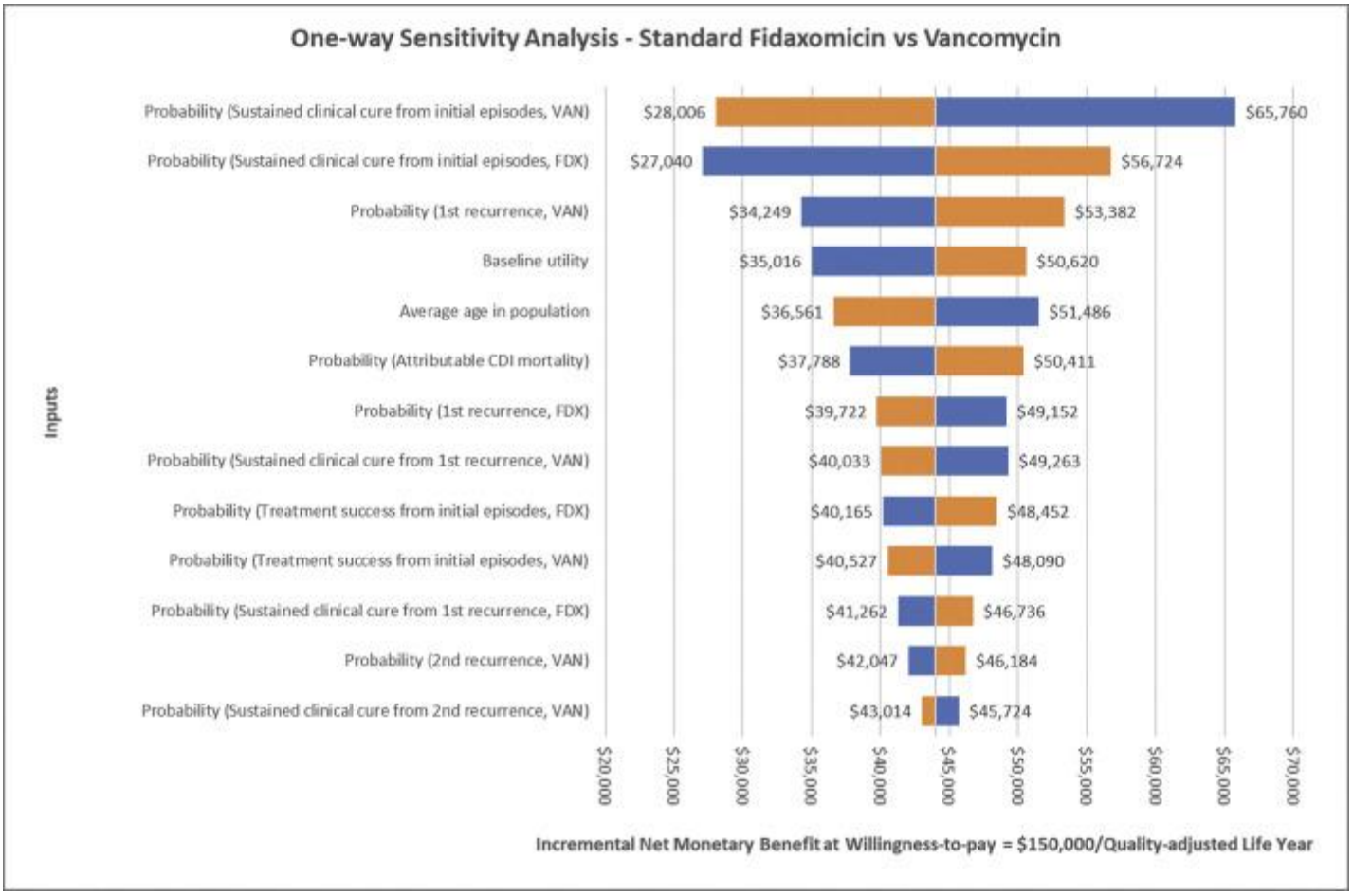

One-way Sensitivity Analysis - Extended-pulsed Fidaxomicin vs Vancomycin
Inputs
Probability (Sustained clinical cure from initial episodes, VAN)
-$13,054
$24,700
Probability (Sustained clinical cure from initial episodes, EPFX)
-$13,099
$14,770
Probability (1st recurrence, VAN)
-$6,811
$12,322
Probability (Sustained clinical cure from 1st recurrence, VAN)
-$1,027
$8,203
Probability (Treatment success from initial episodes, EPFX)
-$549
$7,045
Probability (Treatment success from initial episodes, VAN)
-$533
$7,030
Probability (1st recurrence, EPFX)
-$120
$6,735
Probability (2nd recurrence, VAN)
$987
$5,124
Probability (Attributable CDI mortality)
$1,098
$5,168
Probability (Sustained clinical cure from 1st recurrence, EPFX)
$1,576
$4,583
Probability (Colectomy from recurrence episodes)
$1,815
$4,675
Probability (Sustained clinical cure from 2nd recurrence, VAN)
$1,954
$4,664
Probability (Treatment success from recurrence episodes, VAN)
$2,072
$4,403
-$20,000
-$15,000
-$10,000
-$5,000
$0
$5,000
$10,000
$15,000
$20,000
$25,000
$30,000
Incremental Net Monetary Benefit at Willingness-to-pay = $150,000/Quality-adjusted Life Year


One-way Sensitivity Analysis - Standard Fidaxomicin vs Vancomycin
Inputs
Probability (Sustained clinical cure from initial episodes, VAN)
Probability (Sustained clinical cure from initial episodes, FDX)
Probability (1st recurrence, VAN)
Baseline utility
Average age in population
Probability (Attributable CDI mortality)
Probability (1st recurrence, FDX)
Probability (Sustained clinical cure from 1st recurrence, VAN)
Probability (Treatment success from initial episodes, FDX)
Probability (Treatment success from initial episodes, VAN)
Probability (Sustained clinical cure from 1st recurrence, FDX)
Probability (2nd recurrence, VAN)
Probability (Sustained clinical cure from 2nd recurrence, VAN)
$28,006
$65,760
$27,040
$56,724
$34,249
$53,382
$35,016
$50,620
$36,561
$51,486
$37,788
$50,411
$39,722
$49,152
$40,033
$49,263
$40,165
$48,452
$40,527
$48,090
$41,262
$46,736
$42,047
$46,184
$43,014
$45,724
$20,000
$25,000
$30,000
$35,000
$40,000
$45,000
$50,000
$55,000
$60,000
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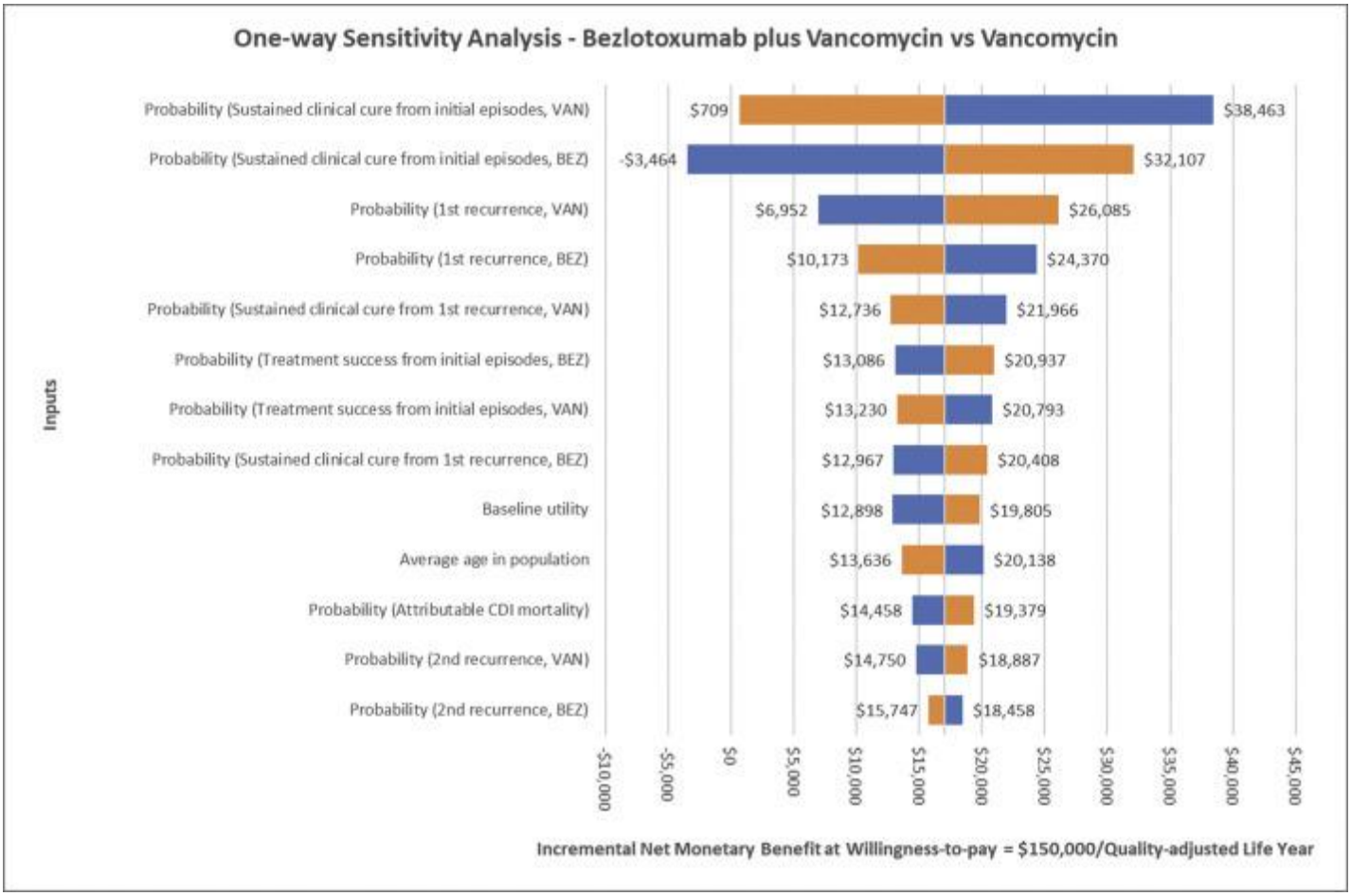
$70,000
Incremental Net Monetary Benefit at Willingness-to-pay = $150,000/Quality-adjusted Life Year


One-way Sensitivity Analysis - Bezlotoxumab plus Vancomycin vs Vancomycin
Inputs
Probability (Sustained clinical cure from initial episodes, VAN)
Probability (Sustained clinical cure from initial episodes, BEZ)
Probability (1st recurrence, VAN)
Probability (1st recurrence, BEZ)
Probability (Sustained clinical cure from 1st recurrence, VAN)
Probability (Treatment success from initial episodes, BEZ)
Probability (Treatment success from initial episodes, VAN)
Probability (Sustained clinical cure from 1st recurrence, BEZ)
Baseline utility
Average age in population
Probability (Attributable CDI mortality)
Probability (2nd recurrence, VAN)
Probability (2nd recurrence, BEZ)
$709
$38,463
-$3,464
$32,107
$6,952
$26,085
$10,173
$24,370
$12,736
$21,966
$13,086
$20,937
$13,230
$20,793
$12,967
$20,408
$12,898
$19,805
$13,636
$20,138
$14,458
$19,379
$14,750
$18,887
$15,747
$18,458
-$10,000
-$5,000
$0
$5,000
$10,000
$15,000
$20,000
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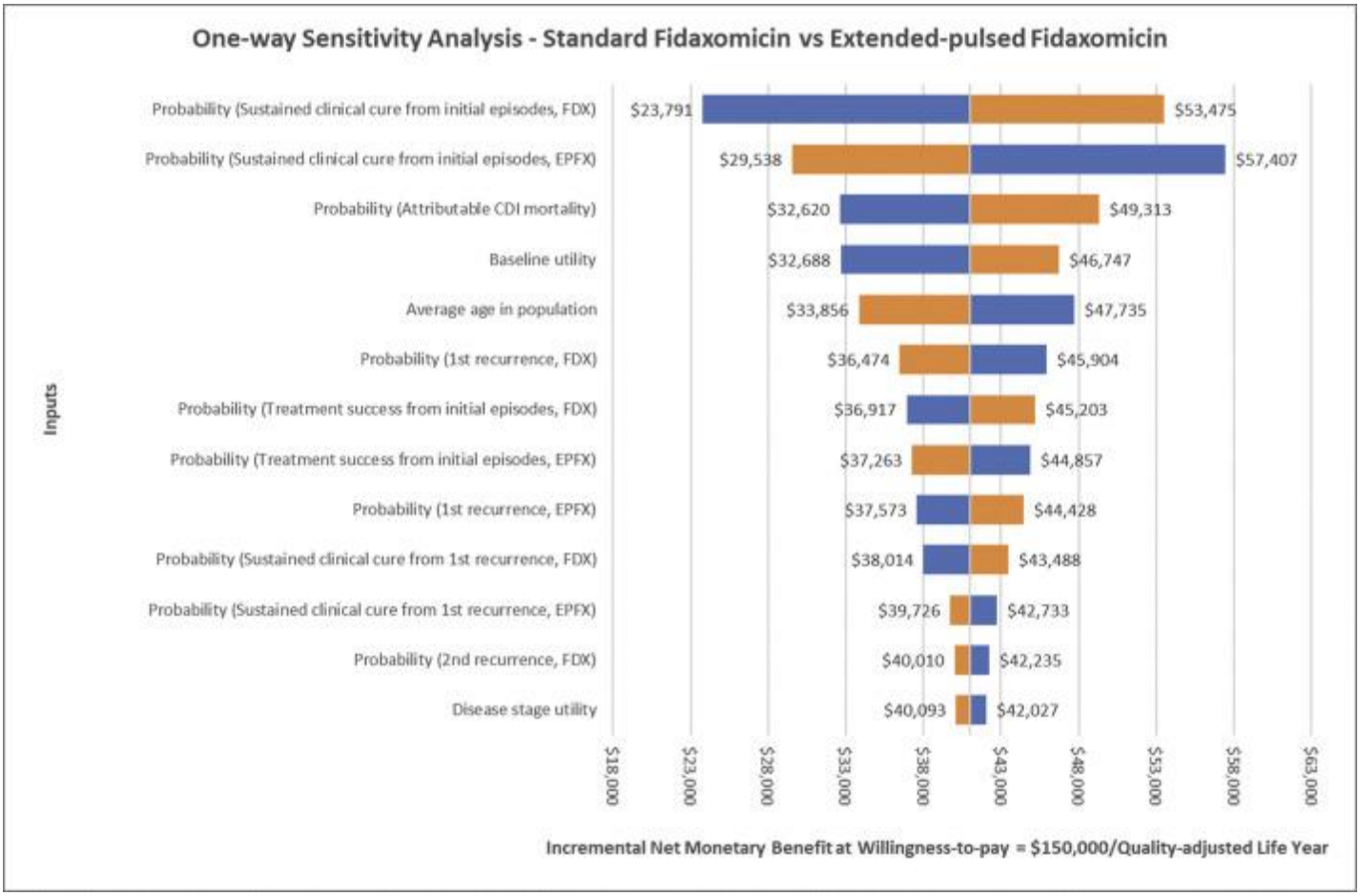
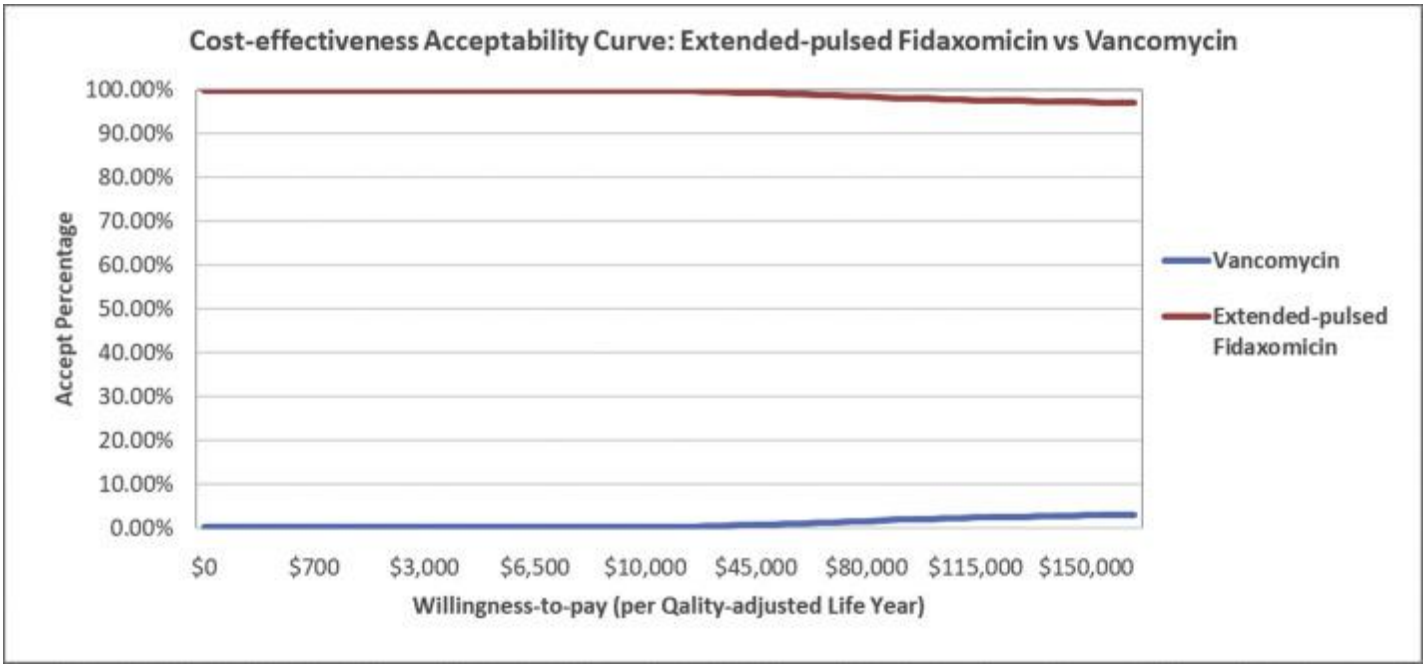
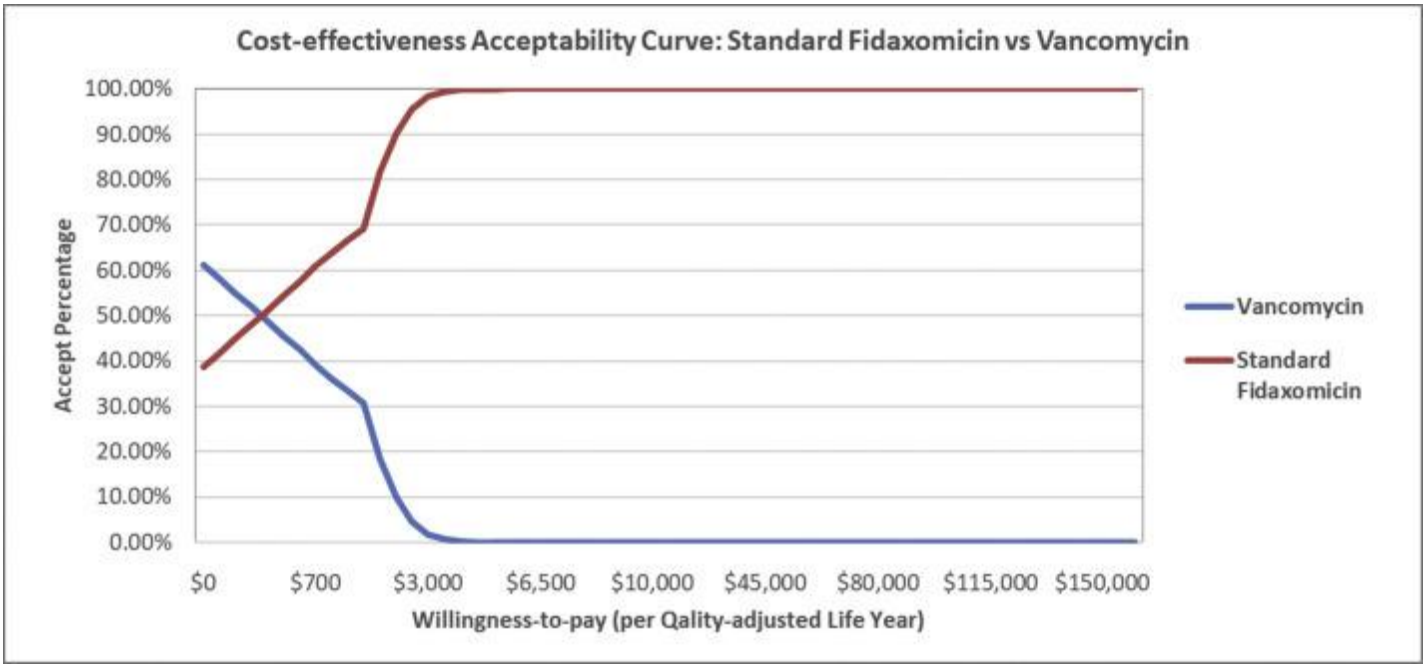
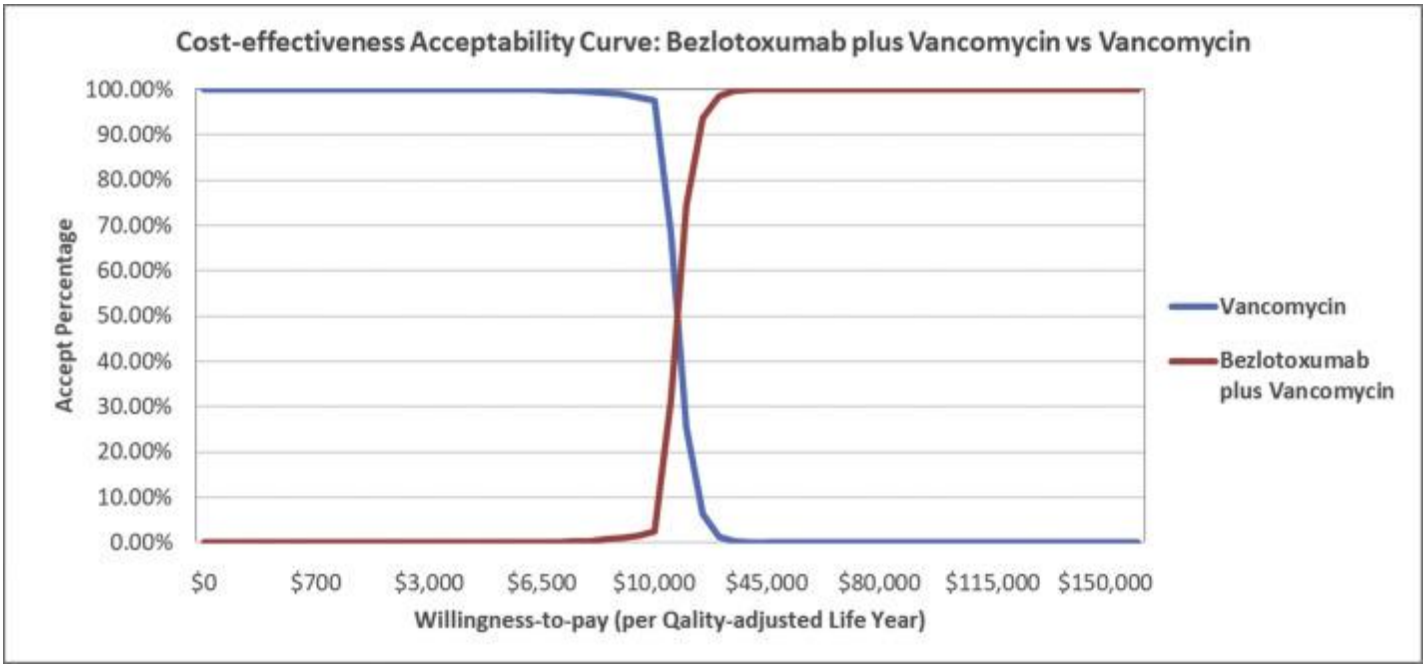
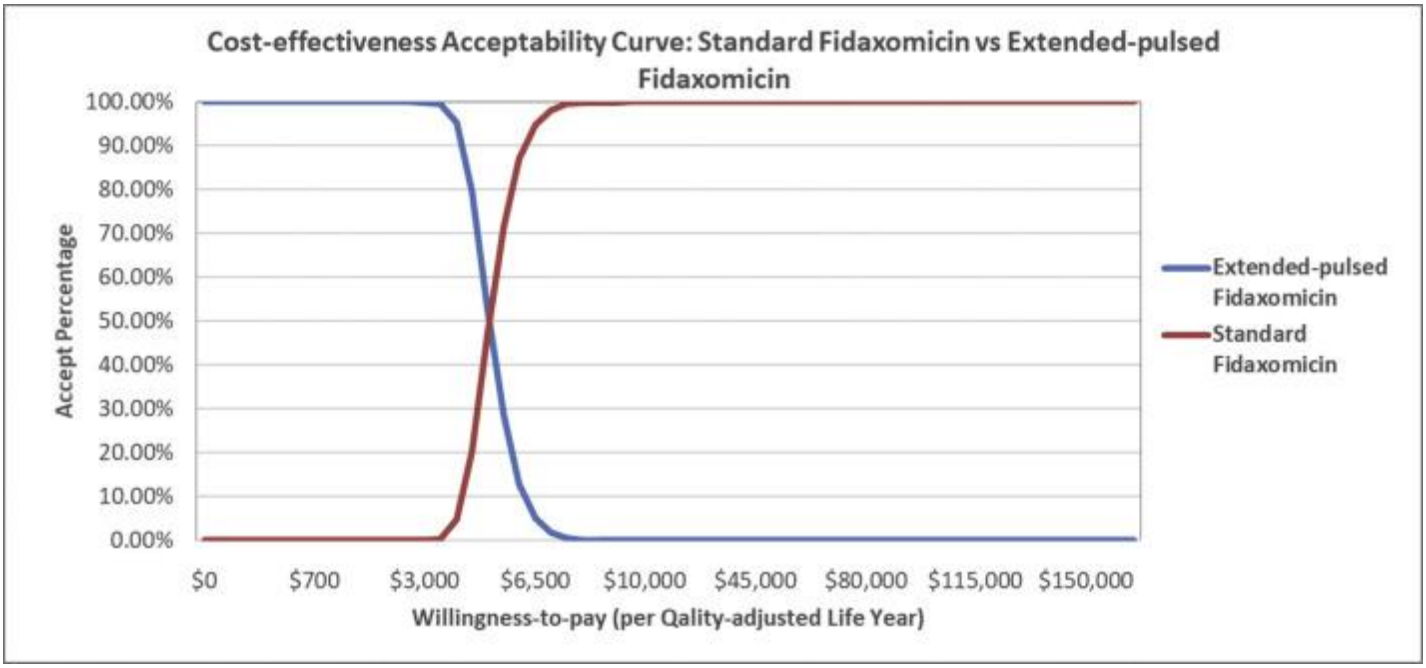
$45,000
Incremental Net Monetary Benefit at Willingness-to-pay = $150,000/Quality-adjusted Life Year

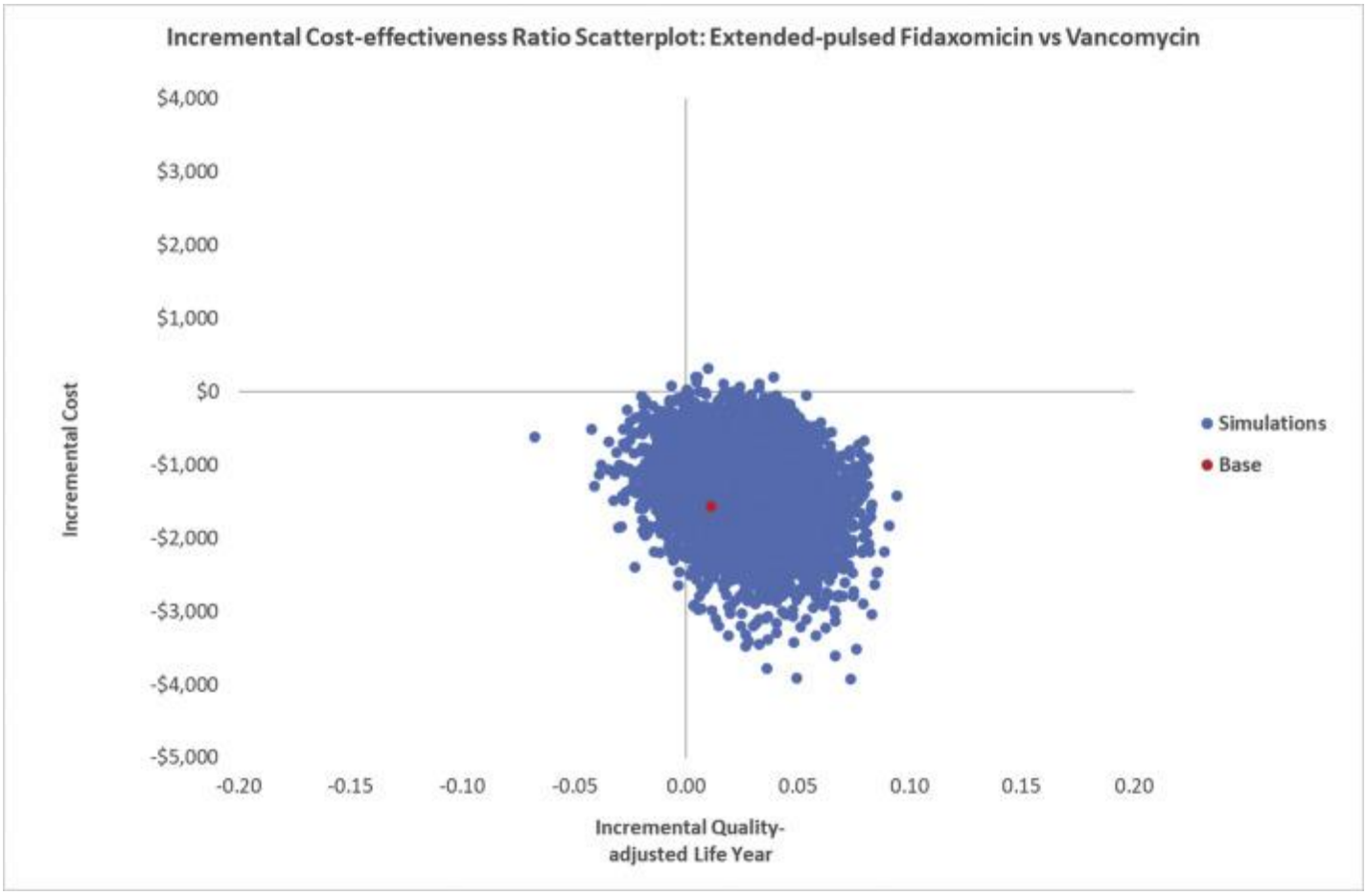

One-way Sensitivity Analysis - Standard Fidaxomicin vs Extended-pulsed Fidaxomicin
Inputs
Probability (Sustained clinical cure from initial episodes, FDX)
$23,791
$53,475
Probability (Sustained clinical cure from initial episodes, EPFX)
$29,538
$57,407
Probability (Attributable CDI mortality)
$32,620
$49,313
Baseline utility
$32,688
$46,747
Average age in population
$33,856
$47,735
Probability (1st recurrence, FDX)
$36,474
$45,904
Probability (Treatment success from initial episodes, FDX)
$36,917
$45,203
Probability (Treatment success from initial episodes, EPFX)
$37,263
$44,857
Probability (1st recurrence, EPFX)
$37,573
$44,428
Probability (Sustained clinical cure from 1st recurrence, FDX)
$38,014
$43,488
Probability (Sustained clinical cure from 1st recurrence, EPFX)
$39,726
$42,733
Probability (2nd recurrence, FDX)
$40,010
$42,235
Disease stage utility
$40,093
$42,027
$18,000
$23,000
$28,000
$33,000
$38,000
$43,000
$48,000
$53,000
$58,000
$63,000
Incremental Net Monetary Benefit at Willingness-to-pay = $150,000/Quality-adjusted Life Year

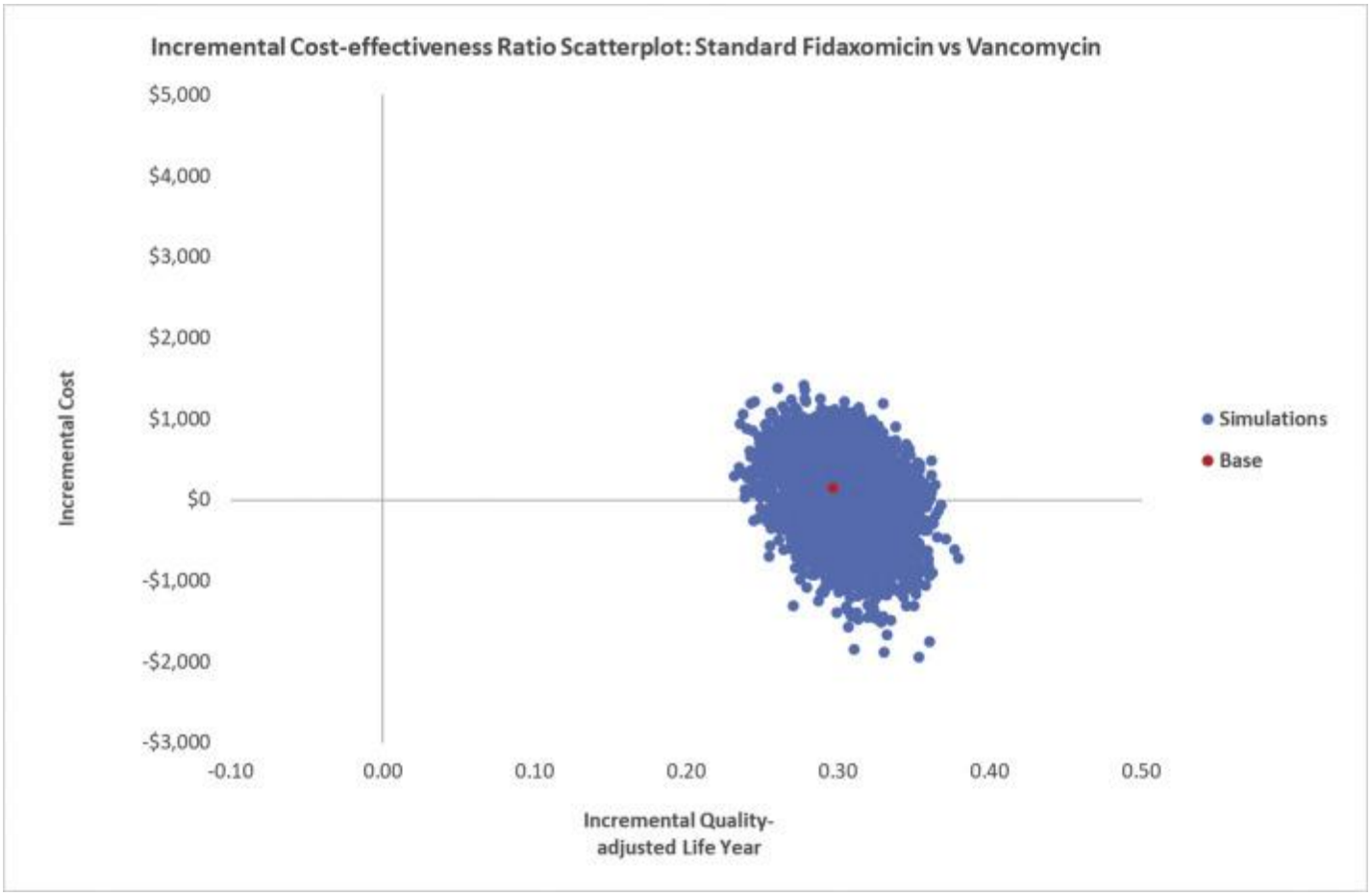

Cost-effectiveness Acceptability Curve: Extended-pulsed Fidaxomicin vs Vancomycin
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Accept Percentage
$0
$700
$3,000
$6,500
$10,000
$45,000
$80,000
$115,000
$150,000
Willingness-to-pay (per Qality-adjusted Life Year)
Vancomycin
Extended-pulsed Fidaxomicin

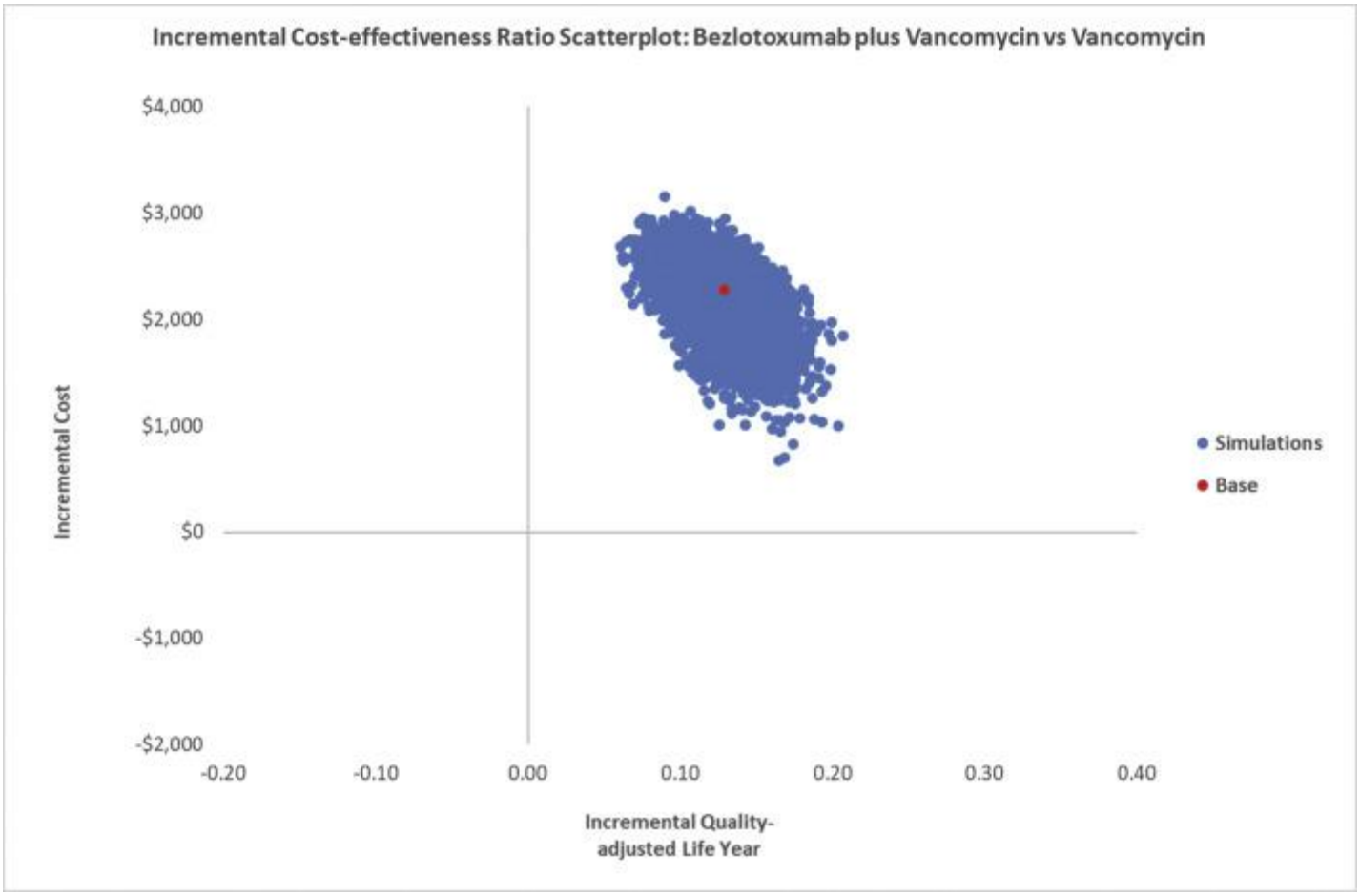

Cost-effectiveness Acceptability Curve: Standard Fidaxomicin vs Vancomycin
Accept Percentage
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
$0
$700
$3,000
$6,500
$10,000
$45,000
$80,000
$115,000
$150,000
Willingness-to-pay (per Qality-adjusted Life Year)
Vancomycin
Standard Fidaxomicin

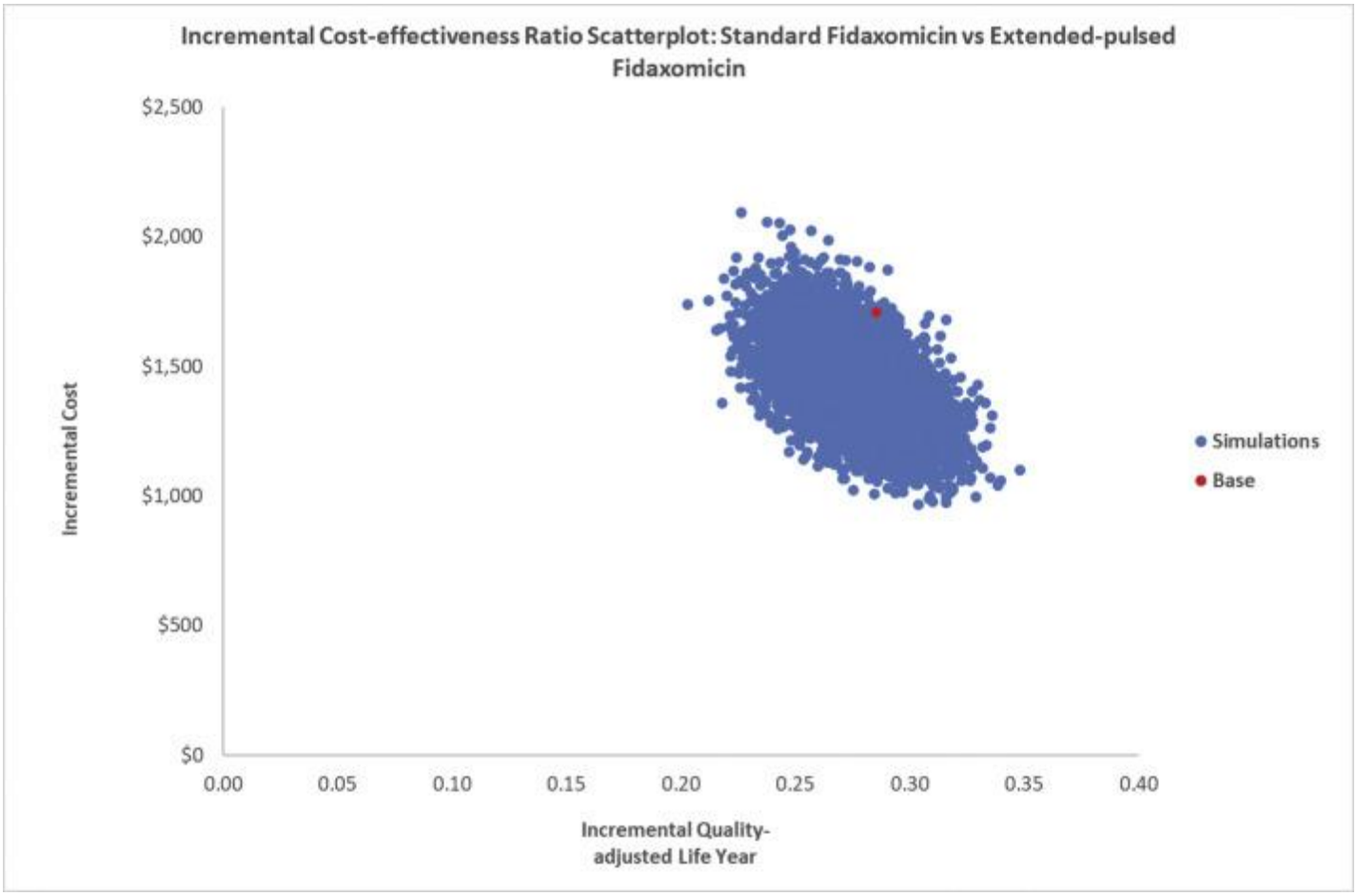

Cost-effectiveness Acceptability Curve: Bezlotoxumab plus Vancomycin vs Vancomycin
Accept Percentage
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
$0
$700
$3,000
$6,500
$10,000
$45,000
$80,000
$115,000
$150,000
Willingness-to-pay (per Qality-adjusted Life Year)
Vancomycin
Bezlotoxumab plus Vancomycin


Cost-effectiveness Acceptability Curve: Standard Fidaxomicin vs Extended-pulsed Fidaxomicin
Accept Percentage
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
$0
$700
$3,000
$6,500
$10,000
$45,000
$80,000
$115,000
$150,000
Willingness-to-pay (per Qality-adjusted Life Year)
Extended-pulsed Fidaxomicin
Standard Fidaxomicin


Incremental Cost-effectiveness Ratio Scatterplot: Extended-pulsed Fidaxomicin vs Vancomycin
$4,000
$3,000
$2,000
$1,000
$0
-$1,000
-$2,000
-$3,000
-$4,000
-$5,000
Incremental Cost
-0.20
-0.15
-0.10
-0.05
0.00
0.05
0.10
0.15
0.20
Incremental Quality-adjusted Life Year
Simulations
Base


Incremental Cost-effectiveness Ratio Scatterplot: Standard Fidaxomicin vs Vancomycin
$5,000
$4,000
$3,000
$2,000
$1,000
$0
-$1,000
-$2,000
-$3,000
Incremental Cost
-0.10
0.00
0.10
0.20
0.30
0.40
0.50
Incremental Quality-adjusted Life Year
Simulations
Base


Incremental Cost-effectiveness Ratio Scatterplot: Bezlotoxumab plus Vancomycin vs Vancomycin
$4,000
$3,000
$2,000
$1,000
$0
-$1,000
-$2,000
Incremental Cost
-0.20
-0.10
0.00
0.10
0.20
0.30
0.40
Incremental Quality-adjusted Life Year
Simulations
Base


Incremental Cost-effectiveness Ratio Scatterplot: Standard Fidaxomicin vs Extended-pulsed Fidaxomicin
$2,500
$2,000
$1,500
$1,000
$500
$0
Incremental Cost
0.00
0.05
0.10
0.15
0.20
0.25
0.30
0.35
0.40
Incremental Quality-adjusted Life Year
Simulations
Base