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Derivation of quality-adjusted life year (QALY) and cost data

Quality-adjusted life years

Individuals in our model gained quality-adjusted life years (QALY) depending on incremental response or non-response to therapy (or no therapy) during each cycle. QALYs were determined by multiplying the length of the time cycle (measured in years) by the health utility value associated with response/non-response. Health utility values ranged from 0 (death) to 1 (perfect health). QALYs were derived from the PROOF study¹³, a natural cohort study of IBS individuals which reported health utility values associated with clinically meaningful “considerable relief” or lack of considerable relief of symptoms.

Costs

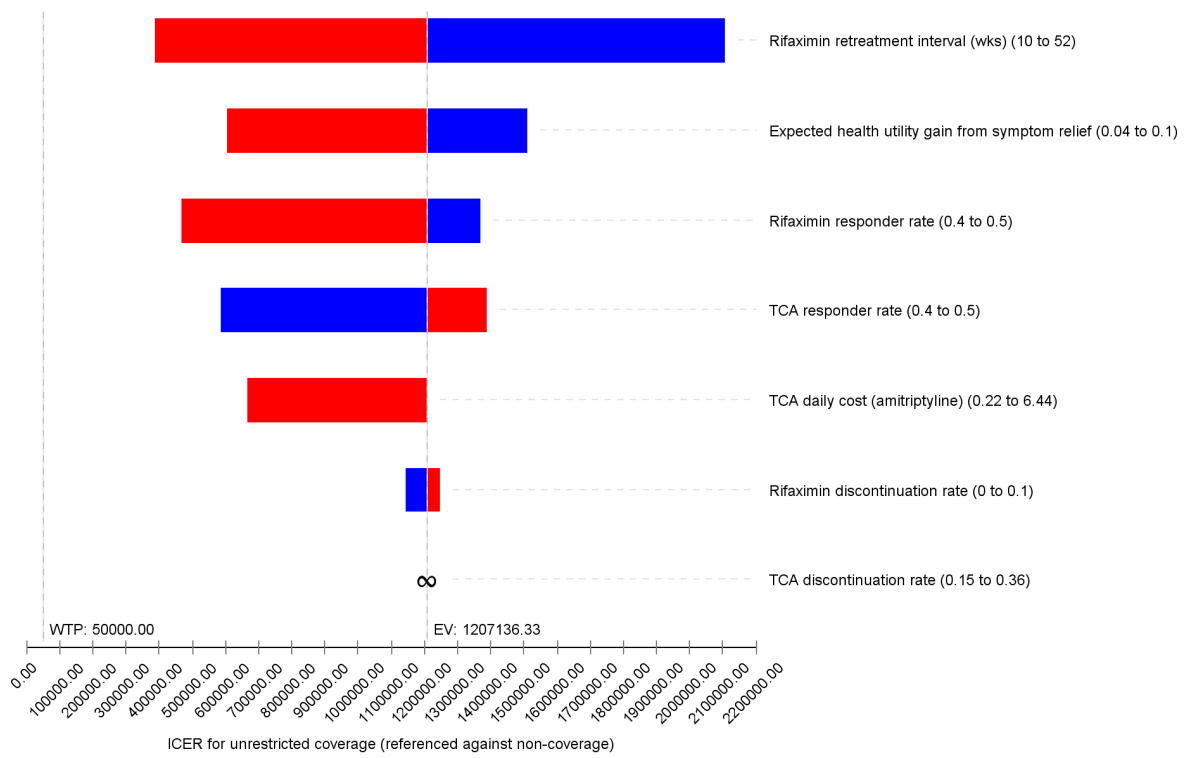
National average payer-reimbursed drug costs were sourced from the October 2016 Medicaid National Average Drug Acquisition Cost (NADAC) database². Non-drug healthcare costs included the cost of an electrocardiogram, outpatient office visits, and average hospitalization cost for a primary diagnosis of IBS in 2016 (ICD-9 564.1) or discounted forward at a 3% annual rate if only earlier data were available. Healthcare utilization rates in the literature were used to determine how often these costs were incurred among therapeutic responders and non-responders.

Work-productivity losses were included in societal analysis and incurred during therapeutic non-response or if no therapy was received. Work-productivity losses were calculated by multiplying the average daily US wage by the number of work-days lost due to undertreated IBS.

Results from a societal perspective

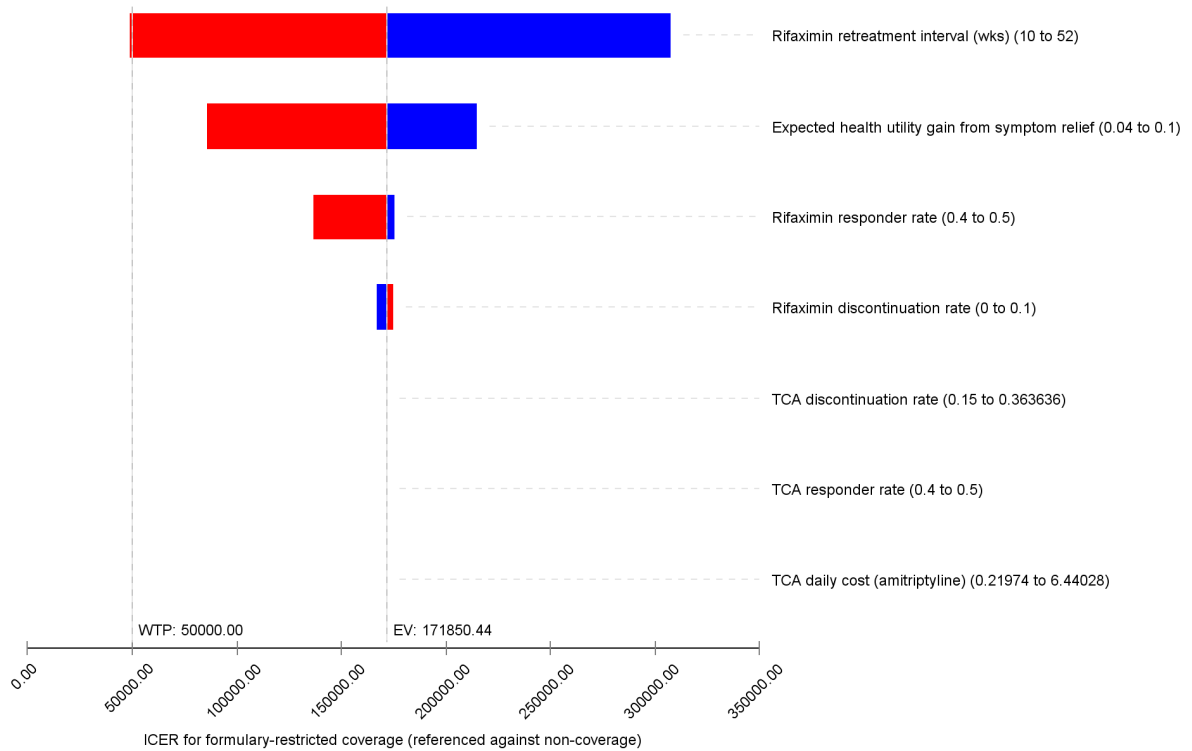
From a societal perspective (**Table 2**), the total cost of complete non-coverage of rifaximin was \$4,355 over one year, compared to \$7,608 with unrestricted coverage or \$4,783 with formulary-restricted coverage. The QALY gained over one year were similar among the three coverage strategies (0.747 to 0.752). Formulary-restricted rifaximin coverage was associated with an additional \$82,375 cost per QALY gained compared to complete non-coverage of rifaximin, based on the national average acquisition cost of rifaximin (\$29.78/pill). In contrast, unrestricted rifaximin access incurred \$1,138,254 additional cost per QALY gained compared to complete non-coverage of rifaximin.

Supplemental Figure 1: Tornado diagram evaluating sensitivity of model inputs from a payer perspective between rifaximin non-coverage and unrestricted coverage.



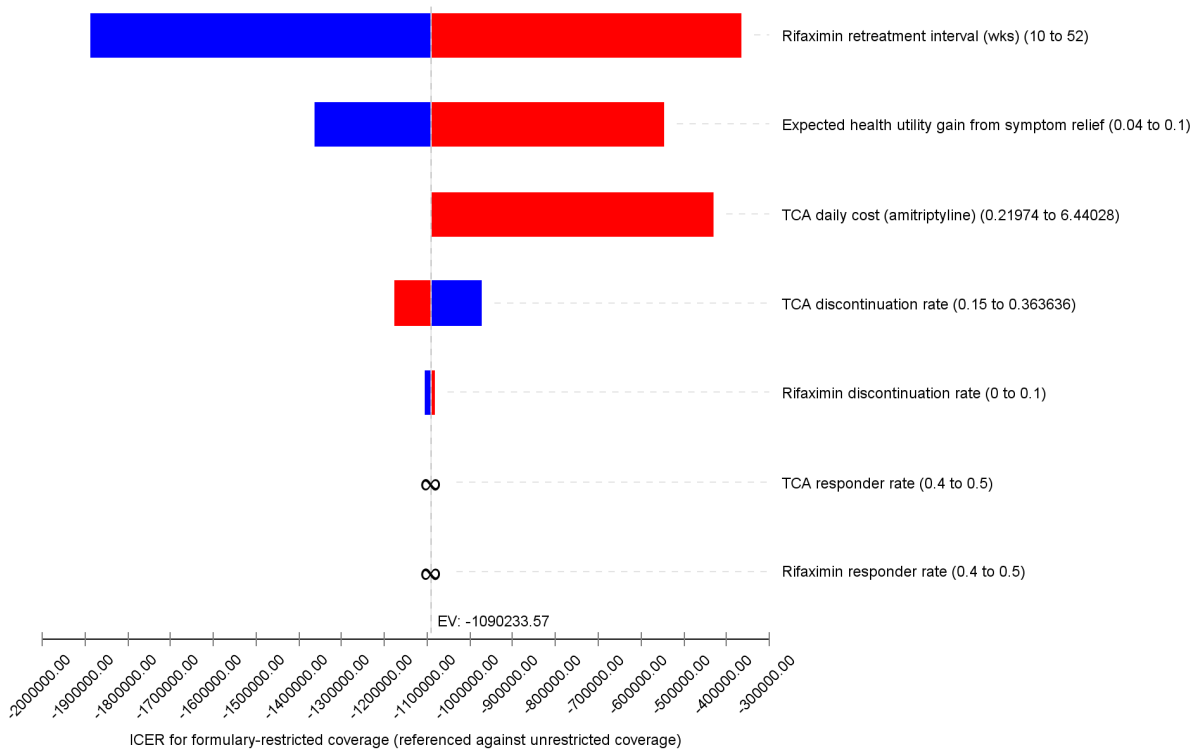
Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER). ICER is most sensitive to the rifaximin retreatment interval.

Supplemental Figure 2: Tornado diagram evaluating sensitivity of model inputs from a payer perspective between rifaximin non-coverage and formulary-restricted coverage.



Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER). ICER is most sensitive to the assumed rifaximin re-treatment interval. A longer assumed rifaximin retreatment interval of at least one year (i.e. prolonged response) is associated with a decrease in ICER below a WTP threshold of \$50,000/QALY-gained.

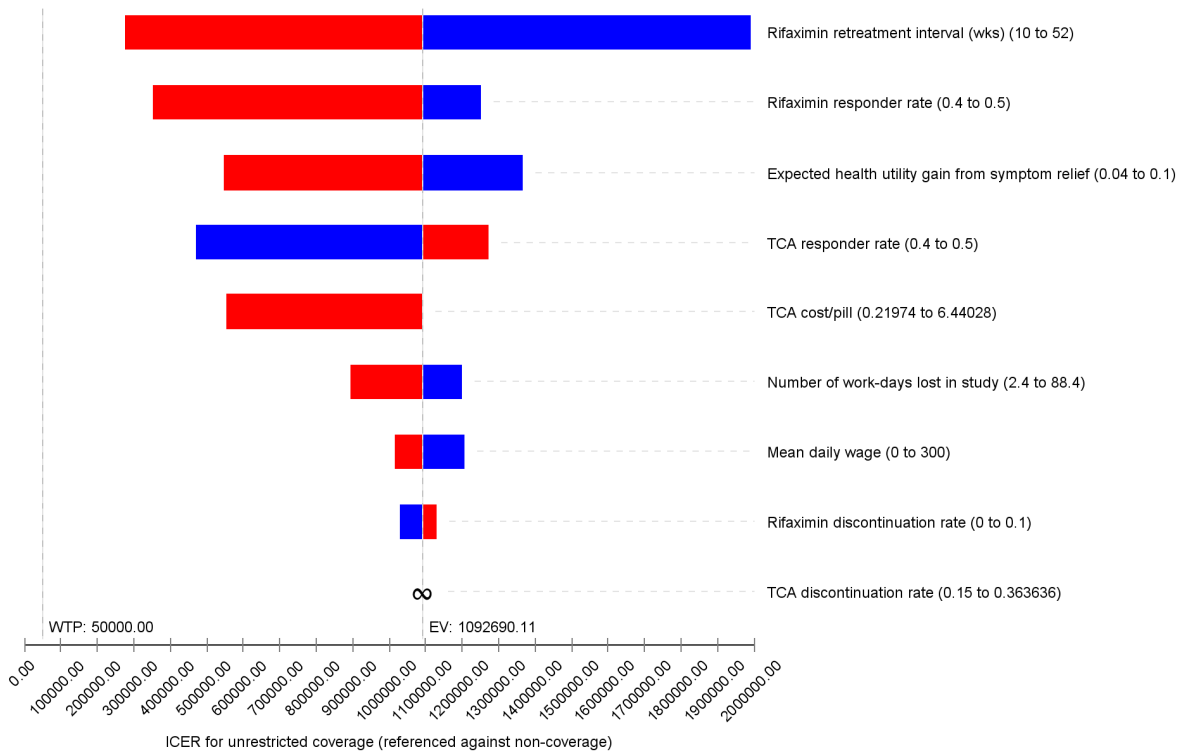
Supplemental Figure 3: Tornado diagram evaluating sensitivity of model inputs from a payer perspective between rifaximin formulary-restricted coverage and unrestricted coverage.



Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER).

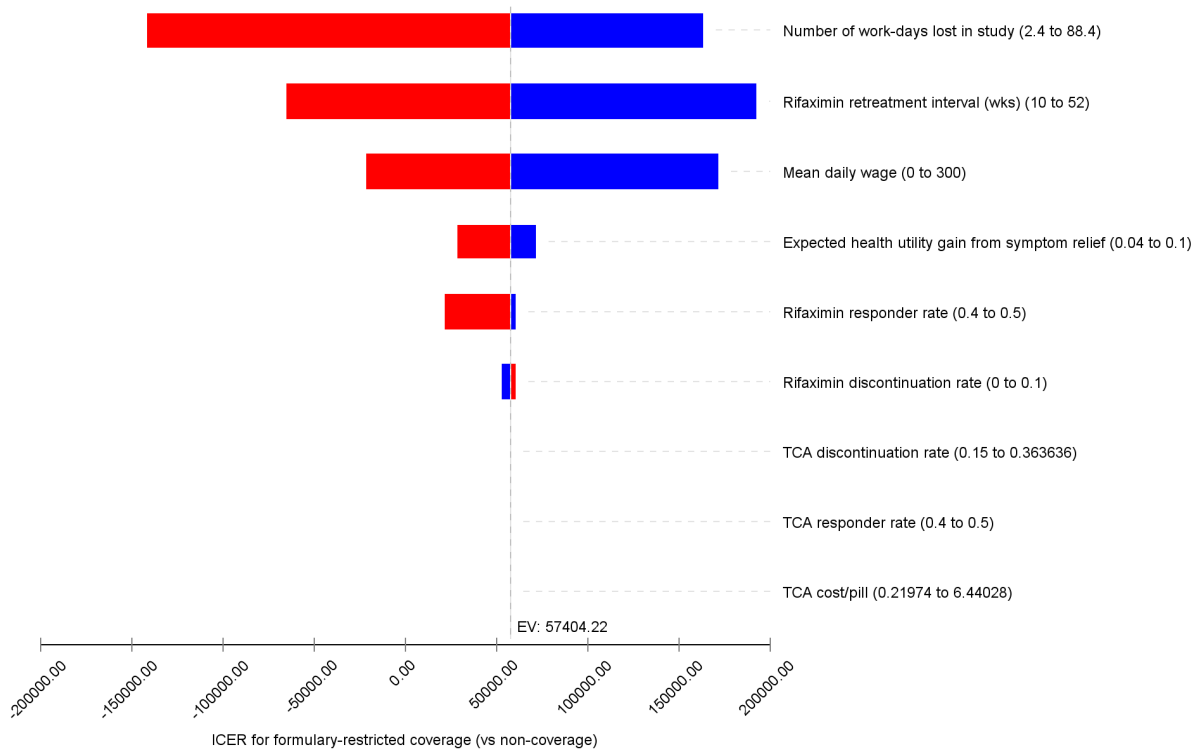
Negative ICER for this analysis specifically represent cost-savings and improved outcomes with formulary-restricted coverage compared to unrestricted coverage which is a stable finding throughout the range of estimates for each model input.

Supplemental Figure 4: Tornado diagram evaluating sensitivity of model inputs from a societal perspective between rifaximin non-coverage and unrestricted coverage.



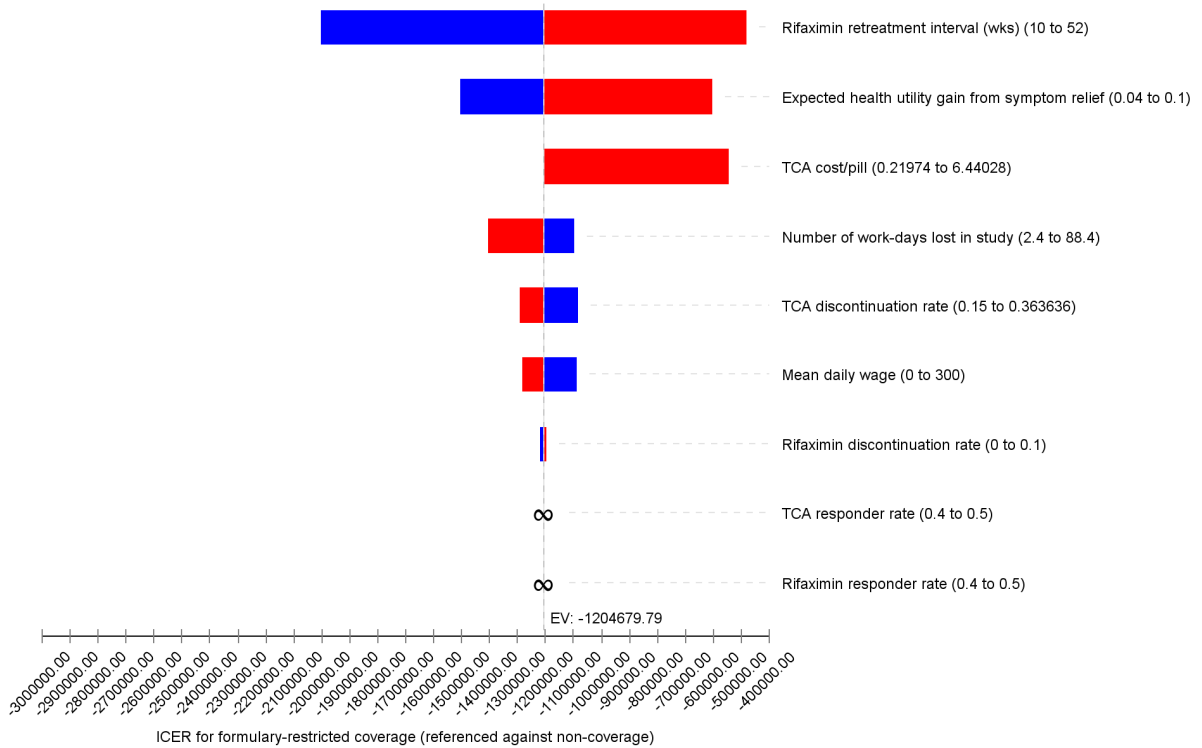
Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER). ICER is most sensitive to the rifaximin retreatment interval.

Supplemental Figure 5: Tornado diagram evaluating sensitivity of model inputs from a societal perspective between rifaximin non-coverage and formulary-restricted coverage.



Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER). From a societal perspective, ICER is most sensitive to the number of work-days lost due to active symptoms, followed by rifaximin retreatment interval and mean daily wage.

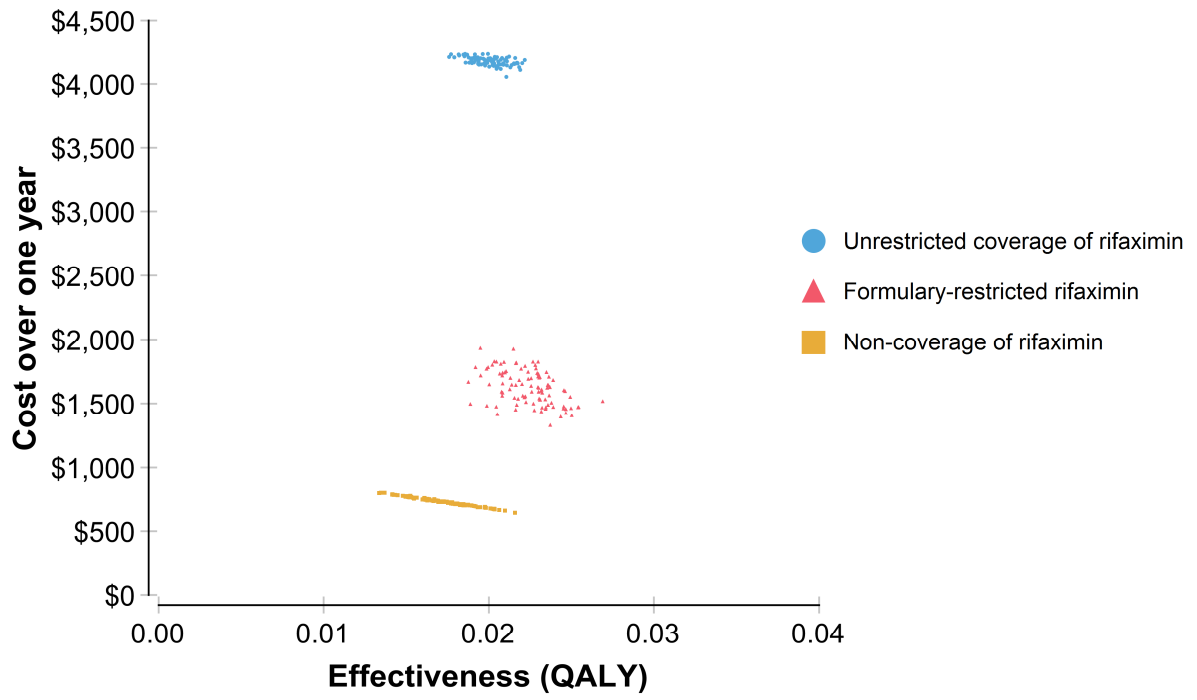
Supplemental Figure 6: Tornado diagram evaluating sensitivity of model inputs from a societal perspective between rifaximin formulary-restricted coverage and unrestricted coverage.



Red indicates that a decrease in the input value (compared to base-case value) leads to a decrease in the ICER. Blue indicates that an increase in the input value (compared to base-case value) leads to a decrease in the ICER compared to the average expected value (base-case ICER).

Negative ICER for this analysis specifically represent cost-savings and improved outcomes with formulary-restricted coverage compared to unrestricted coverage which is a stable finding throughout the range of estimates for each model input.

Supplemental Figure 7: Cost-effectiveness scatterplot of simulations across range of model inputs using probabilistic sensitivity analysis (payer perspective)



Supplemental Table 1: Univariate analysis of effects of rifaximin retreatment interval on cost-effectiveness from a payer perspective

Rifaximin retreatment interval (weeks)	Treatment strategy	Cost	Effectiveness (QALY gained)	Cost-effectiveness (\$/QALY gained)	Incremental cost	Incremental effectiveness	Incremental cost-effectiveness	Net monetary benefit
10	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
10	Formulary-restricted rifaximin	2325.10935	0.022403	103785.643	1597.15398	0.00520135	307065.278	1035.34007
10	Unrestricted rifaximin	6748.68505	0.02005906	336440.714	4423.5757	-0.00234393	-1887243.86	-3739.82579
13	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
13	Formulary-restricted rifaximin	1941.49134	0.022403	86662.129	1213.53597	0.00520135	233311.731	1418.95808
13	Unrestricted rifaximin	5346.0817	0.02005906	266517.037	3404.59037	-0.00234393	-1452510.97	-2337.22245
16	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
16	Formulary-restricted rifaximin	1701.73008	0.022403	75959.933	973.774715	0.00520135	187215.765	1658.71933
16	Unrestricted rifaximin	4469.45461	0.02005906	222814.74	2767.72453	-0.00234393	-1180802.92	-1460.59536
19	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
19	Formulary-restricted rifaximin	1537.68291	0.022403	68637.3778	809.727541	0.00520135	155676.419	1822.76651
19	Unrestricted rifaximin	3869.65713	0.02005906	192913.167	2331.97423	-0.00234393	-994897.415	-860.797873
22	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
22	Formulary-restricted rifaximin	1418.37587	0.022403	63311.8832	690.420504	0.00520135	132738.713	1942.07354
22	Unrestricted rifaximin	3433.44078	0.02005906	171166.569	2015.06491	-0.00234393	-859693.408	-424.581522
25	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
25	Formulary-restricted rifaximin	1327.70252	0.022403	59264.5072	599.747157	0.00520135	115306.057	2032.74689
25	Unrestricted rifaximin	3101.91635	0.02005906	154639.155	1774.21383	-0.00234393	-756938.364	-93.0570956
28	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
28	Formulary-restricted rifaximin	1256.45918	0.022403	56084.4261	528.503812	0.00520135	101608.97	2103.99023
28	Unrestricted rifaximin	2841.43288	0.02005906	141653.329	1584.9737	-0.00234393	-676202.257	167.426383
31	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
31	Formulary-restricted rifaximin	1199.00487	0.022403	53519.8446	471.049502	0.00520135	90562.9314	2161.44454
31	Unrestricted rifaximin	2631.36556	0.02005906	131180.889	1432.36069	-0.00234393	-611092.493	377.493704
34	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
34	Formulary-restricted rifaximin	1151.68955	0.022403	51407.8363	423.734188	0.00520135	81466.1942	2208.75986
34	Unrestricted rifaximin	2458.36894	0.02005906	122556.527	1306.67938	-0.00234393	-557472.688	550.490321
37	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
37	Formulary-restricted rifaximin	1112.04699	0.022403	49638.3158	384.091628	0.00520135	73844.6035	2248.40242
37	Unrestricted rifaximin	2313.42583	0.02005906	115330.71	1201.37883	-0.00234393	-512547.987	695.433433
40	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
40	Formulary-restricted rifaximin	1078.35082	0.022403	48134.2234	350.395451	0.00520135	67366.2515	2282.09859
40	Unrestricted rifaximin	2190.22418	0.02005906	109188.765	1111.87336	-0.00234393	-474361.99	818.635078
43	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
43	Formulary-restricted rifaximin	1049.35643	0.022403	46840.0043	321.401067	0.00520135	61791.8555	2311.09298
43	Unrestricted rifaximin	2084.21346	0.02005906	103903.836	1034.85703	-0.00234393	-441504.273	924.645796
46	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
46	Formulary-restricted rifaximin	1024.14392	0.022403	45714.5964	296.188559	0.00520135	56944.5547	2336.30549
46	Unrestricted rifaximin	1992.03023	0.02005906	99308.2457	967.886306	-0.00234393	-412932.344	1016.82903
49	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
49	Formulary-restricted rifaximin	1002.01866	0.022403	44726.9936	274.063297	0.00520135	52690.8009	2358.43075
49	Unrestricted rifaximin	1911.13474	0.02005906	95275.3806	909.116078	-0.00234393	-387859.019	1097.72452
52	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363				1852.29155
52	Formulary-restricted rifaximin	982.446315	0.022403	43853.345	254.490949	0.00520135	48927.8648	2378.0031
52	Unrestricted rifaximin	1839.57335	0.02005906	91707.8461	857.12703	-0.00234393	-365678.77	1169.28591

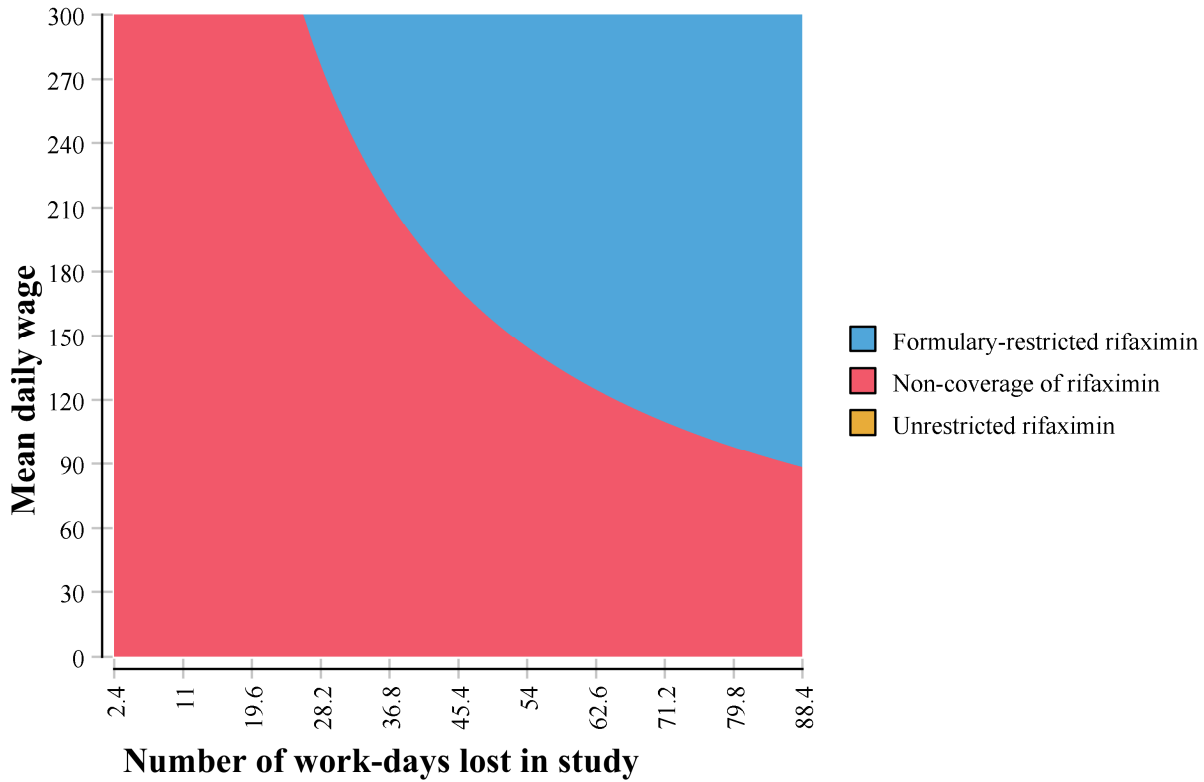
Supplemental Table 2: Univariate analysis of effects of health utility gain from response to therapy on cost-effectiveness from a payer perspective. Higher-than-average health utility gains associated with response to therapy were found to favor a strategy of formulary-restricted rifaximin access over no rifaximin access at willingness-to-pay levels exceeding \$100,000/QALY gained.

Health utility gain	Treatment strategy	Cost	Effectiveness (QALY gained)	Cost-effectiveness (\$/QALY gained)	Incremental cost	Incremental effectiveness	Incremental cost-effectiveness	Net monetary benefit
0.04	Non-coverage of rifaximin	727.955366	0.01376132	52898.6704	0	0	0	1336.24216
0.04	Formulary-restricted rifaximin	1621.80966	0.0179224	90490.6679	893.854297	0.00416108	214813.053	1066.54987
0.04	Unrestricted rifaximin	4177.24559	0.01604725	260309.134	2555.43592	-0.00187515	-1362791.97	-1770.15818
0.044	Non-coverage of rifaximin	727.955366	0.01513745	48089.7004	0	0	0	1542.66192
0.044	Formulary-restricted rifaximin	1621.80966	0.01971464	82264.2436	893.854297	0.00457719	195284.594	1335.38582
0.044	Unrestricted rifaximin	4177.24559	0.01765197	236644.667	2555.43592	-0.00206266	-1238901.79	-1529.44944
0.048	Non-coverage of rifaximin	727.955366	0.01651358	44082.2254	0	0	0	1749.08167
0.048	Formulary-restricted rifaximin	1621.80966	0.02150688	75408.8899	893.854297	0.0049933	179010.878	1604.22177
0.048	Unrestricted rifaximin	4177.24559	0.0192567	216924.278	2555.43592	-0.00225018	-1135659.97	-1288.7407
0.052	Non-coverage of rifaximin	727.955366	0.01788971	40691.2849	0	0	0	1955.50142
0.052	Formulary-restricted rifaximin	1621.80966	0.02329912	69608.2061	893.854297	0.0054094	165240.81	1873.05773
0.052	Unrestricted rifaximin	4177.24559	0.02086142	200237.795	2555.43592	-0.00243769	-1048301.51	-1048.03196
0.056	Non-coverage of rifaximin	727.955366	0.01926584	37784.7646	0	0	0	2161.92118
0.056	Formulary-restricted rifaximin	1621.80966	0.02509136	64636.1914	893.854297	0.00582551	153437.895	2141.89368
0.056	Unrestricted rifaximin	4177.24559	0.02246615	185935.095	2555.43592	-0.00262521	-973422.833	-807.323215
0.06	Non-coverage of rifaximin	727.955366	0.02064198	35265.7803	0	0	0	2368.34093
0.06	Formulary-restricted rifaximin	1621.80966	0.0268836	60327.1119	893.854297	0.00624162	143208.702	2410.72963
0.06	Unrestricted rifaximin	4177.24559	0.02407087	173539.422	2555.43592	-0.00281272	-908527.977	-566.614474
0.064	Non-coverage of rifaximin	727.955366	0.02201811	33061.669	0	0	0	2574.76068
0.064	Formulary-restricted rifaximin	1621.80966	0.02867583	56556.6674	893.854297	0.00665773	134258.158	2679.56558
0.064	Unrestricted rifaximin	4177.24559	0.0256756	162693.209	2555.43592	-0.00300024	-851744.979	-325.905733
0.068	Non-coverage of rifaximin	727.955366	0.02339424	31116.865	0	0	0	2781.18044
0.068	Formulary-restricted rifaximin	1621.80966	0.03046807	53229.8047	893.854297	0.00707384	126360.619	2948.40154
0.068	Unrestricted rifaximin	4177.24559	0.02728032	153123.02	2555.43592	-0.00318775	-801642.333	-85.1969925
0.072	Non-coverage of rifaximin	727.955366	0.02477037	29388.1502	0	0	0	2987.60019
0.072	Formulary-restricted rifaximin	1621.80966	0.03226031	50272.5933	893.854297	0.00748994	119340.585	3217.23749
0.072	Unrestricted rifaximin	4177.24559	0.02888505	144616.185	2555.43592	-0.00337527	-757106.648	155.511748
0.076	Non-coverage of rifaximin	727.955366	0.0261465	27841.4055	0	0	0	3194.01994
0.076	Formulary-restricted rifaximin	1621.80966	0.03405255	47626.6673	893.854297	0.00790605	113059.502	3486.07344
0.076	Unrestricted rifaximin	4177.24559	0.03048977	137004.807	2555.43592	-0.00356278	-717258.93	396.220489
0.08	Non-coverage of rifaximin	727.955366	0.02752263	26449.3352	0	0	0	3400.4397
0.08	Formulary-restricted rifaximin	1621.80966	0.03584479	45245.334	893.854297	0.00832216	107406.527	3754.9094
0.08	Unrestricted rifaximin	4177.24559	0.0320945	130154.567	2555.43592	-0.00375029	-681395.983	636.92923
0.084	Non-coverage of rifaximin	727.955366	0.02889877	25189.8431	0	0	0	3606.85945
0.084	Formulary-restricted rifaximin	1621.80966	0.03763703	43090.7942	893.854297	0.00873827	102291.93	4023.74535
0.084	Unrestricted rifaximin	4177.24559	0.03369922	123956.73	2555.43592	-0.00393781	-648948.555	877.637971
0.088	Non-coverage of rifaximin	727.955366	0.0302749	24044.8502	0	0	0	3813.2792
0.088	Formulary-restricted rifaximin	1621.80966	0.03942927	41132.1218	893.854297	0.00915438	97642.2968	4292.5813
0.088	Unrestricted rifaximin	4177.24559	0.03530395	118322.333	2555.43592	-0.00412532	-619450.894	1118.34671
0.092	Non-coverage of rifaximin	727.955366	0.03165103	22999.4219	0	0	0	4019.69896
0.092	Formulary-restricted rifaximin	1621.80966	0.04122151	39343.7687	893.854297	0.00957048	93396.9796	4561.41726
0.092	Unrestricted rifaximin	4177.24559	0.03690867	113177.884	2555.43592	-0.00431284	-592518.246	1359.05545
0.096	Non-coverage of rifaximin	727.955366	0.03302716	22041.1127	0	0	0	4226.11871
0.096	Formulary-restricted rifaximin	1621.80966	0.04301375	37704.445	893.854297	0.00998659	89505.4388	4830.25321
0.096	Unrestricted rifaximin	4177.24559	0.0385134	108462.139	2555.43592	-0.00450035	-567829.986	1599.76419
0.1	Non-coverage of rifaximin	727.955366	0.03440329	21159.4682	0	0	0	4432.53846
0.1	Formulary-restricted rifaximin	1621.80966	0.04480599	36196.2672	893.854297	0.0104027	85925.2212	5099.08916
0.1	Unrestricted rifaximin	4177.24559	0.04011812	104123.653	2555.43592	-0.00468787	-545116.786	1840.47293

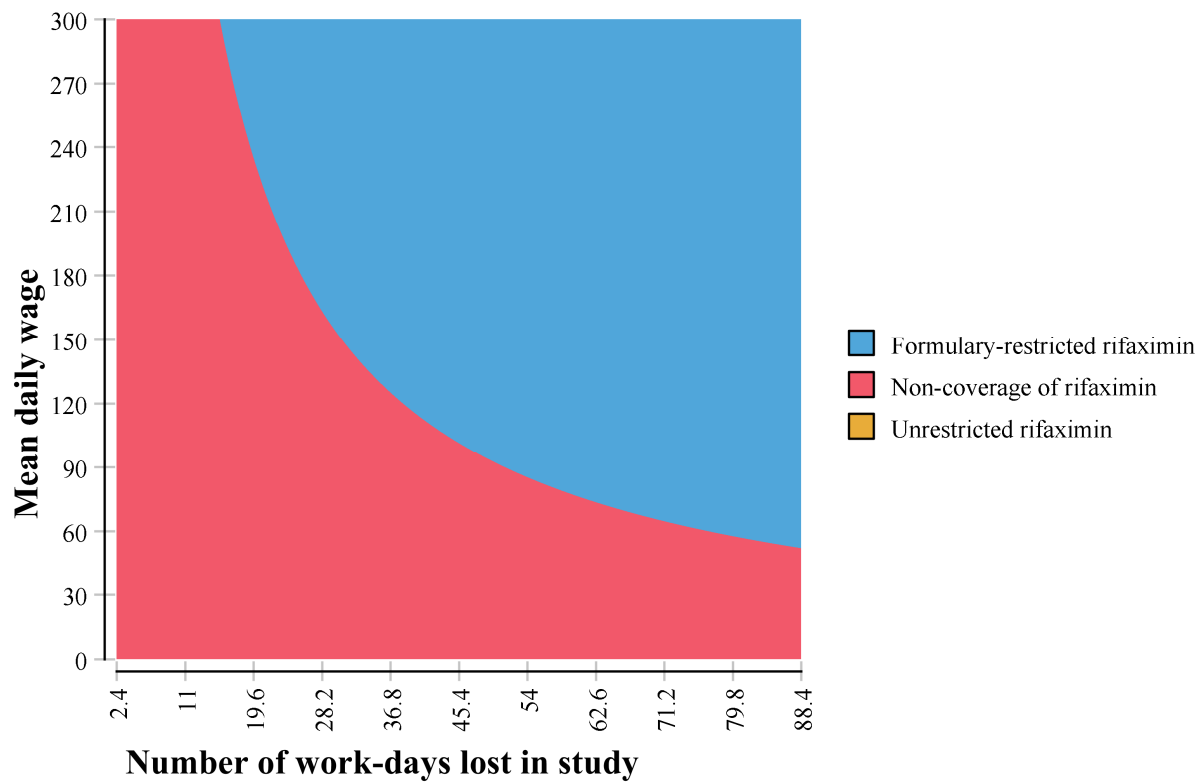
Supplemental Table 3: Univariate analysis of effects of rifaximin retreatment interval on cost-effectiveness from a payer perspective. A rifaximin responder rate less than 46% favored a TCA-only approach.

Health utility gain	Treatment strategy	Cost	Effectiveness (QALY gained)	Cost-effectiveness (\$/QALY gained)	Incremental cost	Incremental effectiveness	Incremental cost-effectiveness	Net monetary benefit
0.4	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.4	Formulary-restricted rifaximin	1623.57057	0.02231289	72763.783	895.615207	0.00511125	175224.374	1723.36352
0.4	Unrestricted rifaximin	4183.68391	0.01972963	212050.849	2560.11334	-0.00258327	-991036.632	-1224.24004
0.41	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.41	Formulary-restricted rifaximin	1621.07328	0.02244068	72238.1689	893.117916	0.00523903	170473.938	1745.02799
0.41	Unrestricted rifaximin	4174.55319	0.02019683	206693.528	2553.47991	-0.00224385	-1137990.81	-1145.02932
0.42	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.42	Formulary-restricted rifaximin	1618.57599	0.02256846	71718.5068	890.620625	0.00536681	165949.714	1766.69246
0.42	Unrestricted rifaximin	4165.42247	0.02066403	201578.458	2546.84648	-0.00190443	-1337327.07	-1065.8186
0.43	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.43	Formulary-restricted rifaximin	1616.0787	0.02269624	71204.6962	888.123333	0.00549459	161635.918	1788.35693
0.43	Unrestricted rifaximin	4156.29175	0.02113123	196689.571	2540.21305	-0.00156501	-1623127.18	-986.607876
0.44	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.44	Formulary-restricted rifaximin	1613.58141	0.02282402	70696.6388	885.626042	0.00562237	157518.204	1810.0214
0.44	Unrestricted rifaximin	4147.16103	0.02159843	192012.189	2533.57962	-0.00122559	-2067227.71	-907.397155
0.45	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.45	Formulary-restricted rifaximin	1611.08412	0.0229518	70194.2384	883.128751	0.00575015	153583.5	1831.68587
0.45	Unrestricted rifaximin	4138.03031	0.02206563	187532.878	2526.94619	-0.00088617	-2851523.39	-828.186433
0.46	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.46	Formulary-restricted rifaximin	1608.58683	0.02307958	69697.4012	880.63146	0.00587794	149819.869	1853.35034
0.46	Unrestricted rifaximin	4128.89959	0.02253283	183239.316	2520.31276	-0.00054676	-4609580.83	-748.975712
0.47	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.47	Formulary-restricted rifaximin	1606.08953	0.02320736	69206.0352	878.134168	0.00600572	146216.393	1875.01482
0.47	Unrestricted rifaximin	4119.76887	0.02300003	179120.184	2513.67933	-0.00020734	-12123670.2	-669.764991
0.48	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.48	Formulary-restricted rifaximin	1603.59224	0.02333514	68720.0506	875.636877	0.0061335	142763.062	1896.67929
0.48	Unrestricted rifaximin	4110.63814	0.02346723	175165.065	2507.0459	0.00013208	18980937	-590.55427
0.49	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.49	Formulary-restricted rifaximin	1601.09495	0.02346292	68239.3594	873.139586	0.00626128	139450.684	1918.34376
0.49	Unrestricted rifaximin	4101.50742	0.02393443	171364.354	2500.41247	0.0004715	5303089.28	-511.343548
0.5	Non-coverage of rifaximin	727.955366	0.01720165	42318.9363	0	0	0	1852.29155
0.5	Formulary-restricted rifaximin	1598.59766	0.02359071	67763.8756	870.642295	0.00638906	136270.8	1940.00823
0.5	Unrestricted rifaximin	4092.3767	0.02440163	167709.182	2493.77904	0.00081092	3075247.02	-432.132827

Supplemental Figure 8: Bivariate analysis of effects of daily wage and days of work-productivity lost on preferred strategy (willingness to pay = \$50,000 per QALY)



Supplemental Figure 9: Bivariate analysis of effects of daily wage and days of work-productivity lost on preferred strategy (willingness to pay = \$100,000 per QALY)



Supplemental Figure 10: Bivariate analysis of effects of daily wage and days of work-productivity lost on preferred strategy (willingness to pay = \$150,000 per QALY)

