

ESTIMATED COST-EFFECTIVENESS OF A 12-WEEK TREATMENT COURSE OF THE FIRST FDA-CLEARED PRESCRIPTION DIGITAL THERAPEUTIC FOR PATIENTS WITH OPIOID USE DISORDER

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BACKGROUND

- It is estimated that 10.3 million individuals in the US misused opioids in 2018 and 2.0 million had an opioid use disorder (OUD).¹
- Altogether, the annual cost of OUD has been estimated to be \$504 billion (2015 \$US).²
- Treatment with pharmacotherapy and counseling services can reduce overall healthcare costs for patients with OUD.³⁻⁵
- Research indicates that most individuals with substance use disorders need at least 3 months in treatment to significantly reduce or stop substance use,⁶ however, treatment engagement and retention can be challenging.⁷
- reSET-O[®] is an FDA-authorized prescription digital therapeutic (PDT) indicated for improving treatment retention in patients with OUD. It is the mobile adaptation of the desktop Therapeutic Education System (TES), an internet-based intervention that combines evidence-based neurobehavioral therapies, including the community reinforcement approach (CRA – a form of cognitive behavioral therapy specific to substance use disorders) in addition to fluency training (FT – a technique used to facilitate and reinforce the learning of new behaviors and skills), and contingency management (CM - a technique to provide immediate rewards for completing lessons and submitting negative urine drug tests).

OBJECTIVE

- To evaluate the cost-effectiveness of reSET-O in conjunction with treatment as usual (reSET-O+TAU) versus TAU in patients with OUD.

METHODS

STUDY DESIGN

- A decision analytic model evaluated the cost-effectiveness of reSET-O+TAU relative to TAU (buprenorphine treatment, counseling services, and urinalysis) alone.
- The perspective of the model was a third-party payer perspective and the time horizon was 3 months.

MODEL INPUTS

Effectiveness

- Effectiveness data were obtained from a published clinical trial by Christensen et al. (2014),⁸ which found that patients treated with TES (CRA+FT+CM) and buprenorphine had higher treatment retention than patients treated with buprenorphine and contingency management without TES (80.4% vs. 64.1%; hazard ratio of treatment dropout: 2.21, P=0.013).

Treatment Costs

reSET-O Cost

- The cost of re-SET-O was assumed to be \$1,500.

TAU-Related Costs

- TAU cost was derived from the sum of its individual components over 12 weeks (office visits [6*\$33] + urinalyses [36*\$70] + buprenorphine 3*\$123: \$3,086 total).

Healthcare Resource Utilization-Related Costs

- Real-world healthcare resource utilization (HCRU) costs of patients with OUD who were treated with buprenorphine were obtained from an administrative claims database evaluation.
 - Adult patients with ≥1 OUD diagnosis, treated with buprenorphine from January 1, 2015 to March 30, 2018, were identified from Truven Health MarketScan[®] Commercial and Medicare Supplemental Research Databases.
 - Adherence to treatment was defined as the proportion of days covered (PDC) by buprenorphine across 12 weeks. Patients with PDC ≥0.8 and <0.8 were categorized as adherent and nonadherent, respectively.^{9,10}
 - Twelve-week HCRU costs for patients categorized as adherent and nonadherent to buprenorphine treatment were estimated.

ANALYSIS

- The incremental cost-effectiveness ratio (ICER) of reSET-O + TAU vs. TAU was calculated as the difference in direct costs (reSET-O cost + TAU + HCRU-related cost vs. TAU + HCRU) incurred over 12 weeks between the two treatment strategies, divided by the difference in buprenorphine treatment retention rate at 12 weeks.

$$ICER = \frac{(Treatment_{reSET-O+TAU} + HCRU_{reSET-O+TAU}) - (Treatment_{TAU} + HCRU_{TAU})}{(Retention_{reSET-O + TAU} - Retention_{TAU})}$$

- HCRU costs were weighted to account for the retention difference observed in reSET-O's pivotal clinical trial (reSET-O+TAU 80%; TAU 64%) by assigning adherent costs to retained patients, and non-adherent costs to non-retained patients using the following formula:

$$HCRU_{Treatment} = HCRUCost_{Adherent} \times Retention_{Treatment} + HCRUCost_{Nonadherent} \times (1 - Retention_{Treatment})$$

METHODS CONT'D

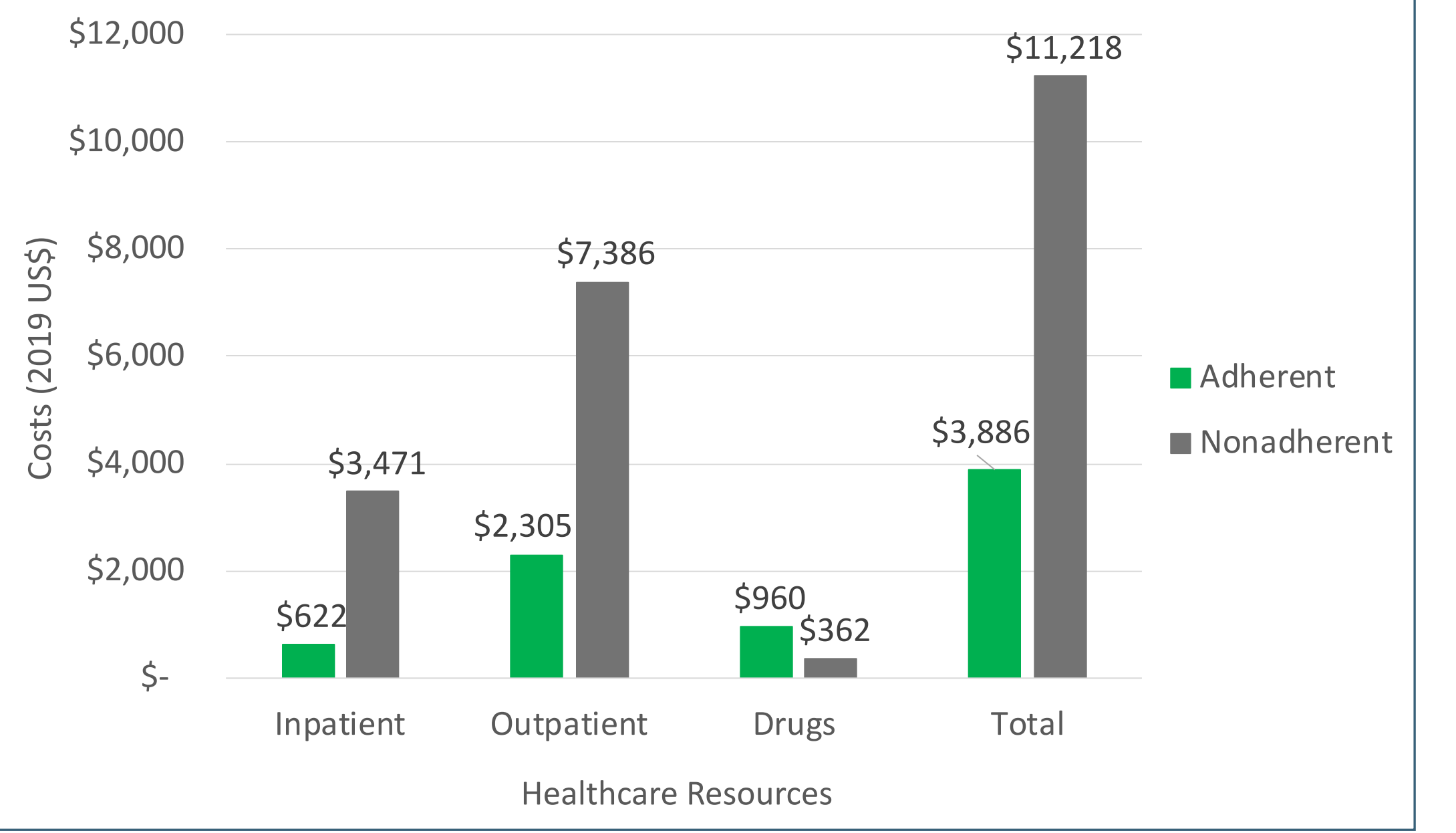
- A Monte Carlo simulation with 1,000 iterations and a probabilistic sensitivity analysis was performed to estimate the probability that reSET-O+TAU would be considered cost-effective at various willingness-to-pay thresholds.

RESULTS

REAL-WORLD HCRU AND COSTS

- From a total of 81,539 adult patients identified with an OUD diagnosis from January 1, 2015 to March 30, 2018, 9,850 (12%) had 12 weeks of continuous enrollment and were treated with buprenorphine.
- Overall, 65.31% of patients treated with buprenorphine were adherent and 34.69% were nonadherent.
- Higher buprenorphine adherence was associated with lower HCRU costs in claims data (\$7,332 less for nonadherent patients than for adherent patients; P<0.001; **Figure 1**).

Figure 1. Average 12-week healthcare resource utilization (HCRU) costs in 2019 US dollars (USD) of patients adherent and nonadherent to buprenorphine, separated into inpatient, outpatient, and drug costs. Costs were estimated based on MarketScan[®] healthcare claims of adults with opioid use disorder.



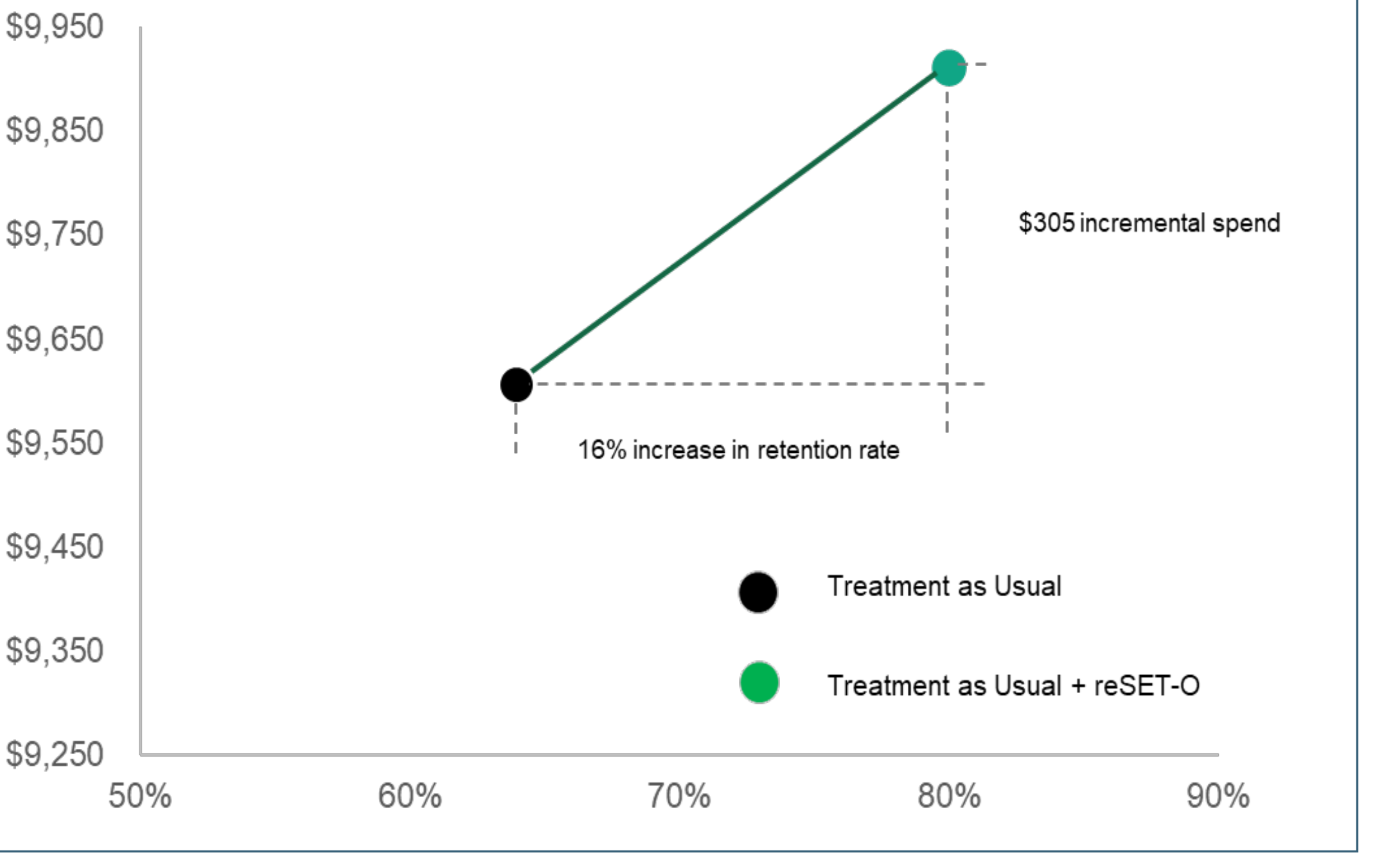
MODEL TREATMENT AND HCRU COSTS

- The weighted-average 12-week per-patient HCRU_{reSET-O + TAU} costs and HCRU_{TAU} costs were \$5,323 and \$6,519, respectively.
- The combined 12-week per-patient treatment and HCRU costs for reSET-O+TAU and TAU were \$9,910 and \$9,605, respectively.

COST EFFECTIVENESS MODEL

- Twelve-week per-patient total costs were \$305 more for those receiving reSET-O+TAU than those receiving TAU (**Figure 2**).

Figure 2. Incremental cost effectiveness ratio (ICER) was assessed by calculating the projected costs difference between treatment-as-usual (TAU) and TAU+ reSET-O, divided by the difference in retention rates observed in reSET-O's clinical trial. ICER is projected to be \$18.70 per 1% increase in retention, or approximately \$300 for the 16% increase in retention, as observed in reSET-O's clinical trial. The number needed to treat was determined to be: 6.1



- The ICER for reSET-O+TAU was \$18.70 per 1 percentage-point increase in retention.
- The probabilistic sensitivity analysis demonstrated the certainty that reSET-O+TAU would be considered cost-effective versus TAU across a range of willingness-to-pay thresholds (**Table 1** and **Figure 3**).
- The probability that reSET-O would be considered cost-effective was greater than 92% for third party payers with willingness-to-pay thresholds of \$6,000 or more for a one percentage-point increase in the buprenorphine treatment retention rate (**Figure 3**).

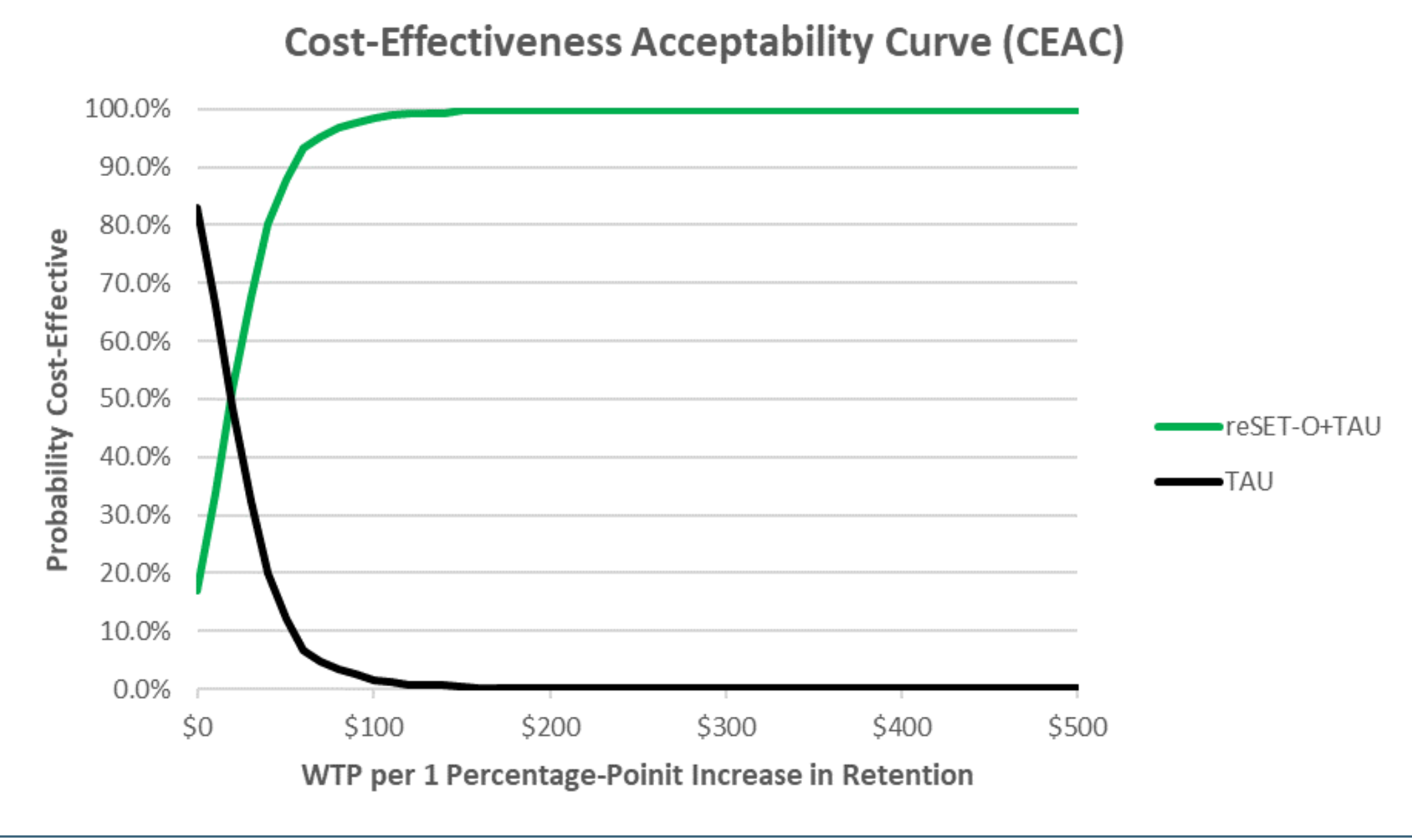
RESULTS CONT'D

Table 1. Specifics of the input parameters used for the probabilistic sensitivity analysis.

Parameter	Point Estimate	Low	High	Distribution	Standard Error
Number of Units					
Office visits (12 weeks)	6.00	5.40	6.60	gamma	0.306
Urinalysis (12 weeks)	36.00	32.40	39.60	gamma	1.837
Buprenorphine (12 weeks)	3.00	2.70	3.30	gamma	0.153
Costs					
reSET-O (12 weeks)	\$1,500	1350.00	1650.00	gamma	76.531
Office visits (per session)	\$33	29.70	36.30	gamma	1.684
Urinalysis (unit cost)	\$70	63.00	77.00	gamma	3.571
Buprenorphine (per month)	\$123	110.53	135.09	gamma	6.266
HCRU					
reSET-O+TAU	\$5,323	4904	5873	gamma	247.194
TAU	\$6,519	6539	7394	gamma	218.112
Retention Rates					
reSET-O+TAU	80.40%	72.36%	88.44%	beta	0.041
TAU	64.10%	57.69%	70.51%	beta	0.033

HCRU, healthcare resource utilization; TAU, treatment as usual.

Figure 3. Cost-effectiveness acceptability. Lines labeled reSET-O+TAU and TAU indicate the probability of a payer considering the incremental cost-effectiveness ratio of reSET-O in conjunction with treatment as usual (reSET-O+TAU) acceptable or unacceptable, respectively, as a function of the willingness-to-pay (WTP) threshold per 1 percentage-point increase in the buprenorphine treatment retention rate.



DISCUSSION

- The findings are limited by the assumptions of the model due to uncertainty around some inputs. However, while no model is free of bias, the inputs for this model were carefully selected to reflect contemporary treatment patterns.
- The addition of reSET-O to treatment-as-usual may be cost-effective for increasing OUD treatment retention rates.
- These findings are consistent with prior studies which have shown an association between better patient OUD treatment retention and improved clinical and humanistic patient outcomes.

CONCLUSION

- The results demonstrate an incremental cost effectiveness ratio for reSET-O+TAU vs TAU of \$18.70 per percentage-point increase in buprenorphine retention, or about \$300 for the 16% increase in retention in treatment observed in clinical trials.

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