RTI (h)(s)
Health Solutions

Cost-Effectiveness Analysis of CAB-LA for PrEP in the United States

Davis AE, Brogan AJ, Mellott CE, Fraysse J, Oglesby A

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Contributors and Disclosures

- Collaborator affiliations
  - RTI Health Solutions, Research Triangle Park, NC, USA
  - ViiV Healthcare, Research Triangle Park, NC, USA
  - ViiV Healthcare, Amsterdam, Netherlands
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Background and Objective

Pre-exposure prophylaxis (PrEP)

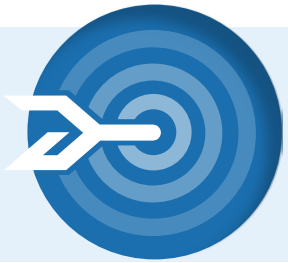
- Effective in preventing HIV in individuals who are at an increased risk of infection[1]
- First approved for adults in the US in 2012

Oral PrEP

- High adherence required to be effective[2]
- Only 1 oral PrEP option (FTC/TDF) is recommended for use by cisgender women[2]
- Underutilized by at-risk individuals[3]

CAB-LA administered every 2 months

- Demonstrated a superior reduction in HIV-1 acquisition compared with daily oral FTC/TDF in MSM, TGW, and cisgender women[4,5]
- Recently approved in the US as PrEP for individuals at risk of acquiring HIV-1 infection



Objective:

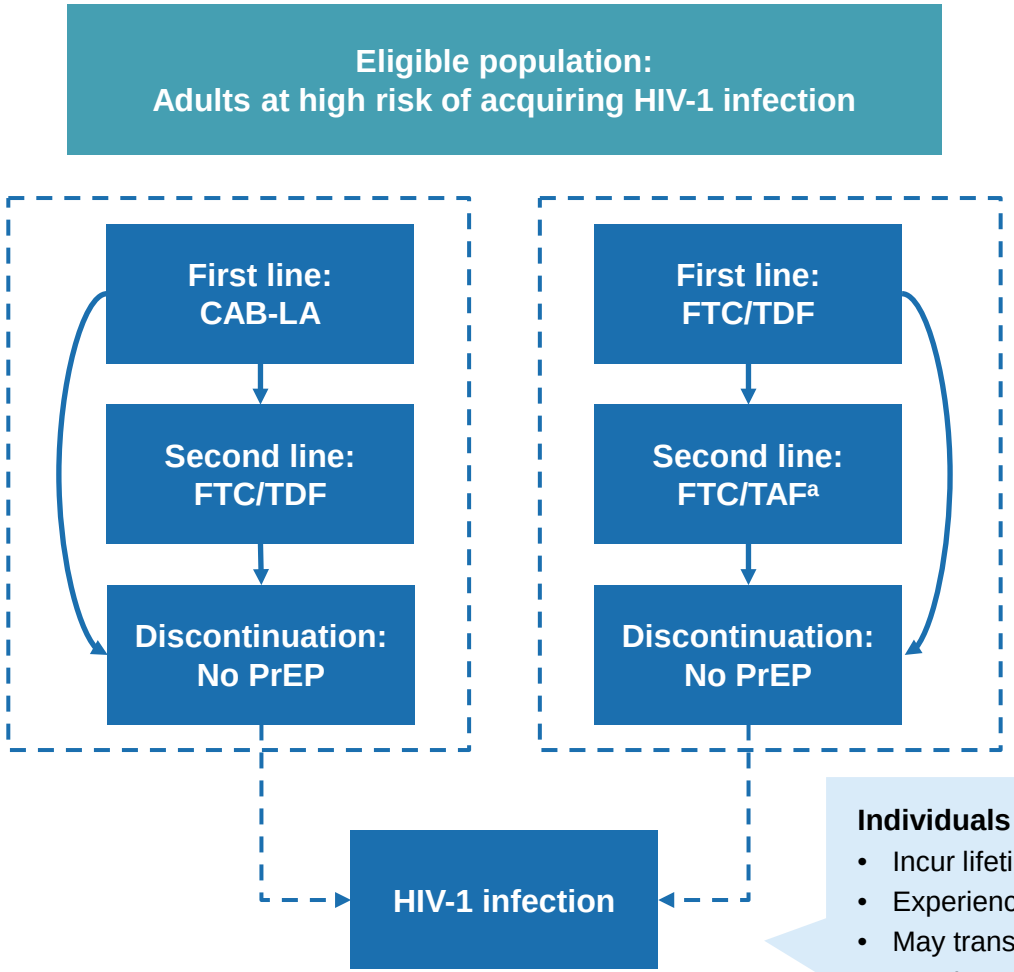
To estimate the cost-effectiveness of CAB-LA over an individual's remaining lifetime from a healthcare sector perspective

CAB-LA = cabotegravir long-acting; FTC = emtricitabine; HIV = human immunodeficiency virus; MSM = men who have sex with men; TDF = tenofovir disoproxil fumarate; TGW = transgender women; US = United States.

[1] CDC (2021c); [2] CDC (2021d); [3] CDC (2021a); [4] Landovitz et al. (2021); [5] Marzinke et al. (2021).

Model Overview

A Markov model to compare PrEP options was developed with a 1-month cycle length, a 5-year duration of HIV risk, and a lifetime time horizon.



Eligible individuals

- Enter the model initiating CAB-LA or generic FTC/TDF
- Can choose to continue their initial PrEP option, transition to a second option, or discontinue PrEP over time

Individuals receiving PrEP

- Are at a reduced risk of acquiring HIV-1 infection
- Incur PrEP-related costs
- May experience injection site reactions

Individuals who acquire HIV-1 infection

- Incur lifetime HIV-related costs
- Experience losses in quality of life
- May transmit HIV-1 infection to their partners
- Rarely, may develop PrEP-related breakthrough resistance

TAF = tenofovir alafenamide.

[a] FTC/TAF is not recommend for use by cisgender women.

Inputs and Assumptions

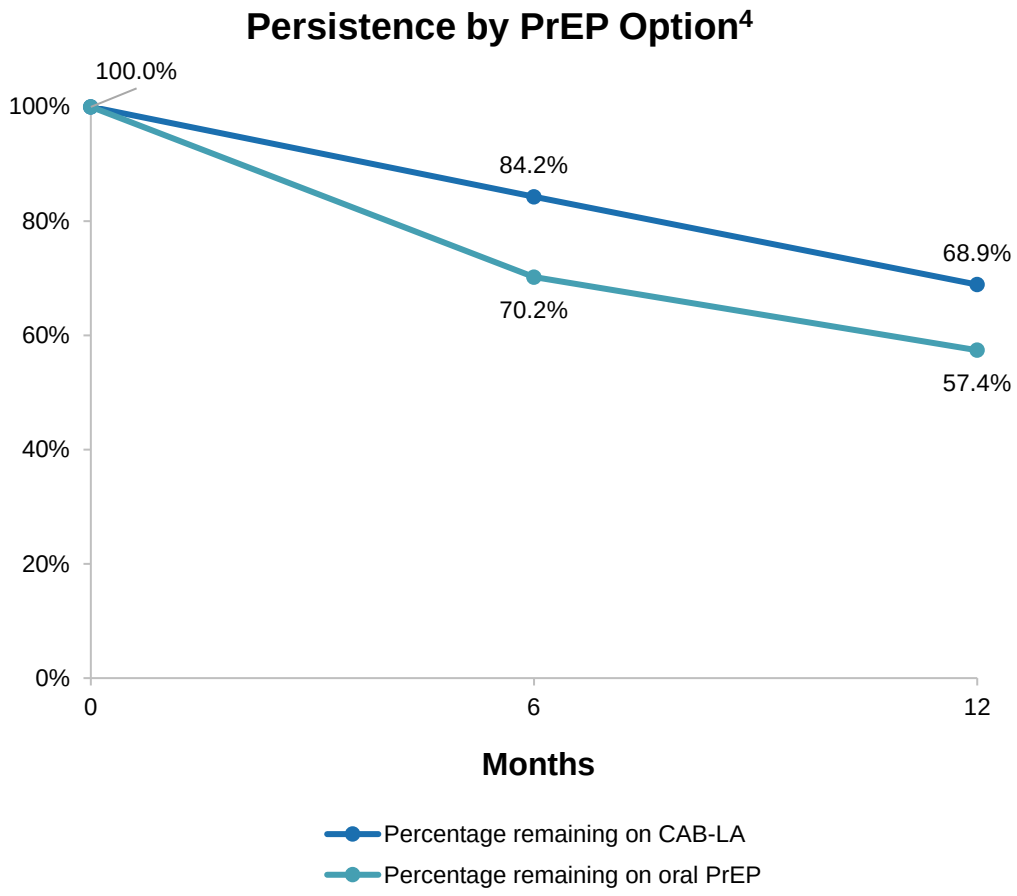
Population and PrEP Use Characteristics

Parameter	Value
PrEP-eligible[1] population distribution	
MSM and TGW (HPTN 083)[2]	92.2%
At-risk cisgender women (HPTN 084)[2]	7.8%
PrEP use characteristics	
Percentage with high adherence[a] to oral PrEP[3]	70.0%
Percentage with high adherence to CAB-LA	100%[b]
Percentage of MSM and TGW who transition from FTC/TDF to FTC/TAF[c] each month[4]	0.7%
Among individuals who discontinue CAB-LA, percentage who transition to FTC/TDF to cover PK tail[5]	50%
Percentage covering PK tail who discontinue FTC/TDF each month[5]	20%

[a] High adherence indicates 4+ doses of oral PrEP per week.

[b] Modeled individuals receiving CAB-LA were assumed to have perfect adherence because they have regular visits to receive injections and thus are monitored as in a clinical trial.

[c] FTC/TAF is not recommended for cisgender women.

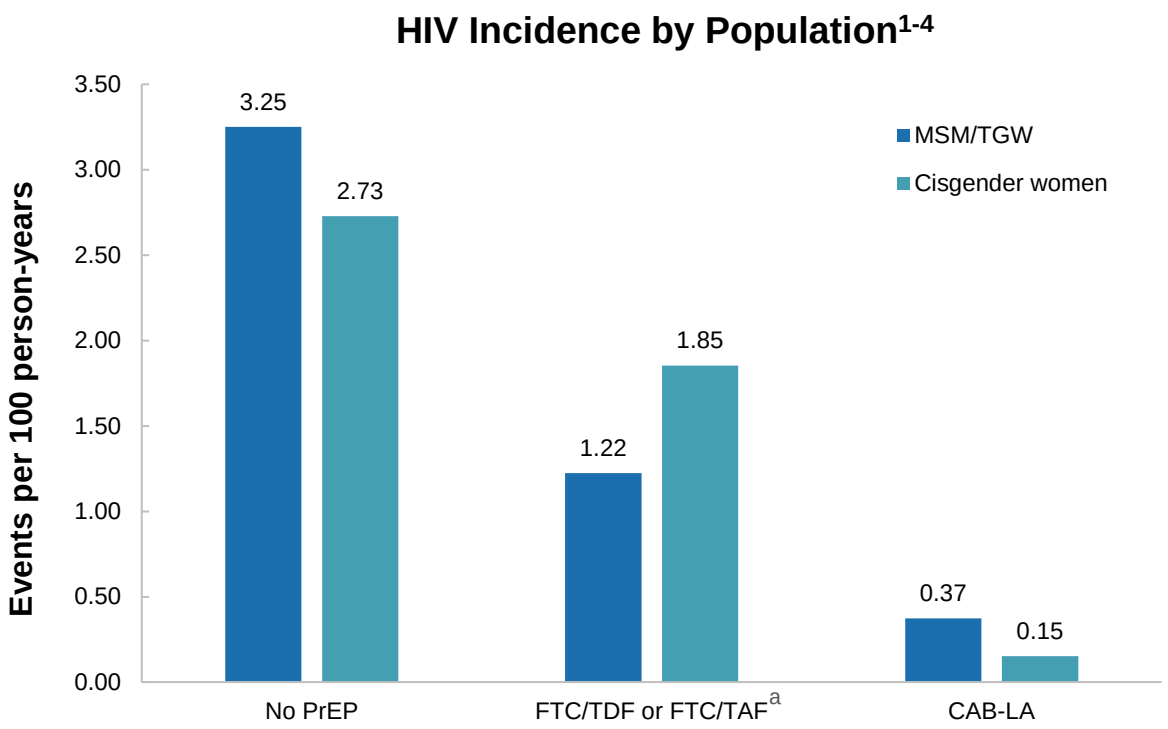


HPTN = HIV Prevention Trial Network; PK = pharmacokinetics.

[1] CDC (2021b); [2] CDC (2021a); [3] ViiV data on file (2020b); [4] Oglesby et al. (2021); [5] Assumption.

Inputs and Assumptions

Clinical Data and Health Effects



[a] MSM and TGW only; FTC/TAF is not recommend for use by cisgender women. FTC/TAF efficacy set at parity with FTC/TDF.

Clinical data and health effects		
Injection site reaction incidence (CAB-LA)	MSM and TGW	Cisgender women
Mild	30.0%[3,5]	25.6%[6]
Moderate	48.0%[3,5]	12.0%[6]
Severe	2.9%[3,5]	0.1%[6]
Lifetime secondary transmissions associated with each HIV infection[7]	0.8	
Life-years lost due to HIV infection[8]	5.7	
QALYs lost due to HIV infection[7]	4.5	
Breakthrough resistance incidence[3,9]	INSTI	NRTI[a]
CAB-LA	0.16%	0.00%
FTC/TDF and FTC/TAF[b]	0.00%	0.19%

[a] Cisgender women are assumed to have similar breakthrough resistance as MSM/TGW from HPTN 083.

[b] MSM and TGW only; FTC/TAF is not recommend for use by cisgender women.

INSTI = integrase strand transfer inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; QALY = quality-adjusted life-year.

[1] Mera et al. (2019); [2] Calculated based on information from Smith et al. (2018), US Census Bureau (2020), and AtlasPlus (2021); [3] Landovitz et al. (2021); [4] ViiV data on file (2021a); [5] ViiV data on file (2020a); [6] ViiV data on file (2021b); [7] Farnham et al. (2013); [8] Calculated using data from Farnham et al. (2013) and Xu et al. (2020); [9] Marzinke et al. (2021).

Inputs and Assumptions

PrEP and HIV-Related Costs

PrEP costs	Year 1[a]	Year 2+[a]
Monthly wholesale acquisition cost[1]		
CAB-LA[b]	$2,158	$1,850
FTC/TDF	$30	$30
FTC/TAF	$2,039	$2,039
Annual administration and visit costs[2]		
CAB-LA	$746	$640
Oral PrEP	$368	$368
Annual monitoring costs (MSM and TGW/cisgender women)[2]		
CAB-LA	$1,060/$903	$950/$794
FTC/TDF	$763/$575	$803/$615
FTC/TAF	$776/NA[c]	$817/NA[c]
Injection site reaction management costs per episode		
Mild	$0.00	NA
Moderate[1]	$4.51	NA
Severe[1,2]	$187.58	NA

NA = not applicable

[1] Red Book (2022); [2] RBRVS (2021); [3] Cohen et al. (2020); [4] Beck et al. (2011).

HIV-related costs	Value
Discounted lifetime HIV-related care cost[d,3]	$939,946
PrEP-related breakthrough resistance costs[e]	
INSTI incremental cost[1]	$17,199
NRTI incremental cost[1]	$17,875
Years of differentiation due to resistance[4]	16.2

[a] Individuals on CAB-LA are assumed to have 7 injections in year 1 and 6 injections in years 2+.

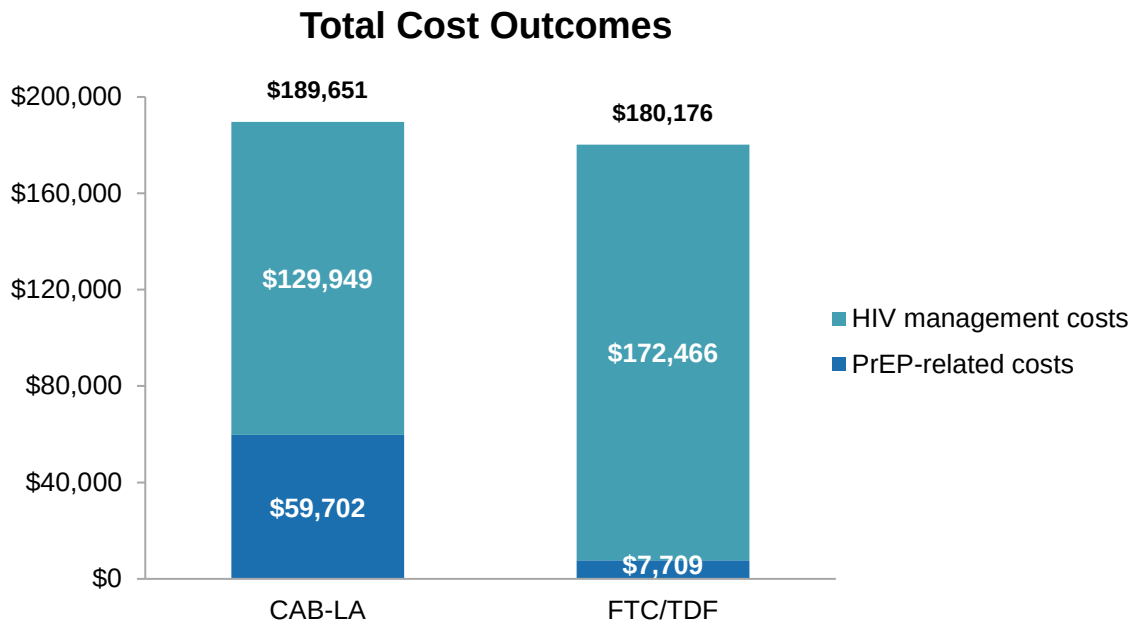
[b] CAB-LA 1-month cost was derived from the 2-month vial cost.

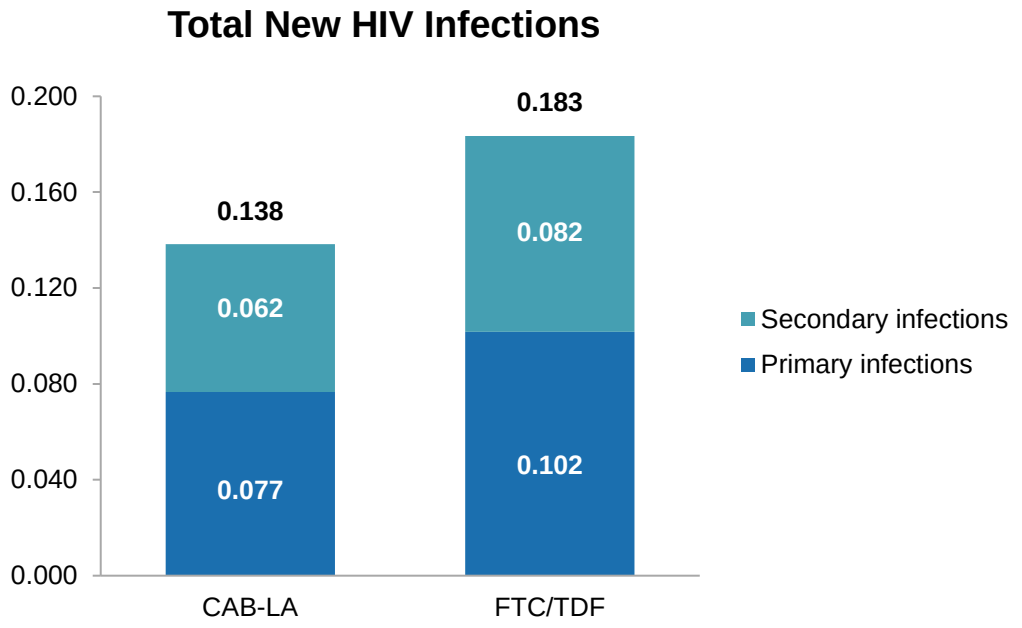
[c] FTC/TAF is not recommended for use by cisgender women.

[d] Applied to primary and secondary HIV-1 infections.

[e] Individuals without resistance are assumed to receive DOVATO, the lowest-cost single-tablet regimen, whereas individuals with INSTI and NRTI resistance are assumed to receive SYMTUZA and TIVICAY + PREZCOBIX, respectively.

Average Per-Person Base-Case Results



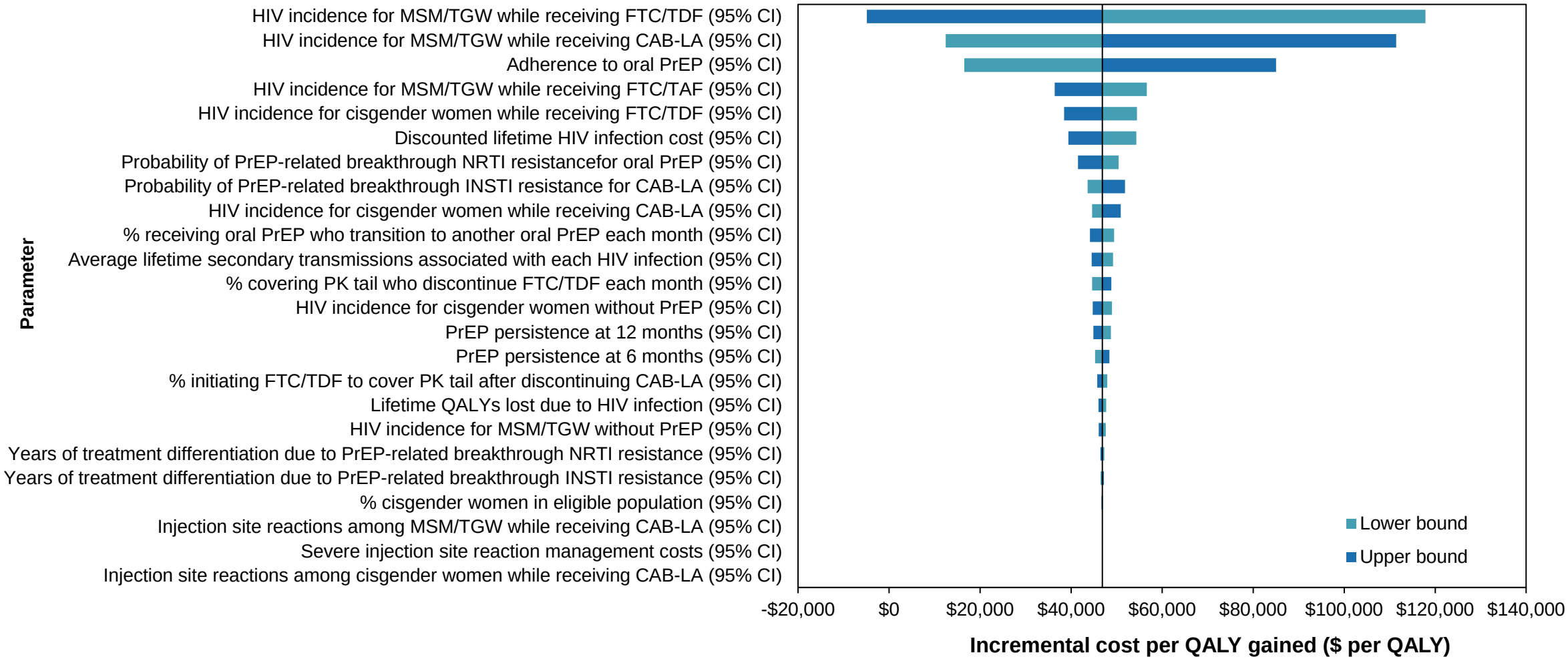


Model outcome	CAB-LA	FTC/TDF	Absolute difference
Total costs	$189,651	$180,176	$9,476
Total QALYs lost due to HIV	0.618	0.821	−0.202
Incremental cost per QALY gained	$46,843		

CAB-LA is cost-effective[1] compared with FTC/TDF, with an incremental cost of $46,843 per QALY gained.

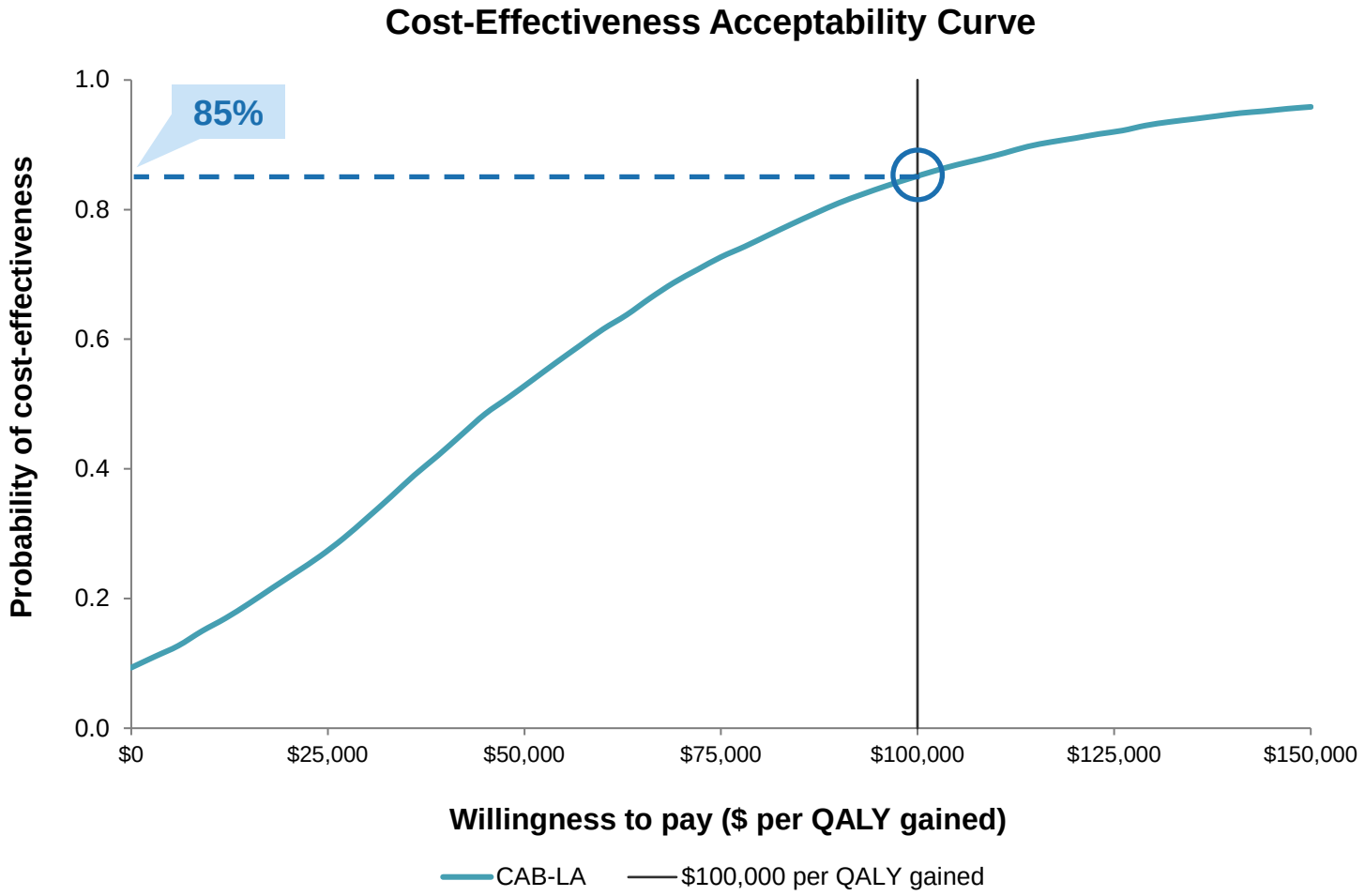
[1] Neumann et al. (2014).

One-Way Sensitivity Analysis Results



Probabilistic Sensitivity Analysis Results

CAB-LA was cost-effective[1] compared with FTC/TDF in 85% of simulations at a willingness-to-pay threshold of $100,000 per QALY gained.



[1] Neumann et al. (2014).

Scenario Analysis Results

Scenario analysis assessed the impact of varying:

- Comparator
- PrEP adherence
- Population subgroups
- High-risk duration

Scenario	Incremental cost per QALY gained
Base case[a]	$46,843
Real-world PrEP use	
CAB-LA vs. no PrEP[1]	CAB-LA dominant[b]
Real-world oral PrEP adherence (57.9%)[2]	CAB-LA dominant[b]
Population subgroups	
Among MSM/TGW[3]	$61,074
Among Black MSM[4]	CAB-LA dominant[b]
Among Hispanic MSM[4]	$84,438
Among White MSM[4]	$107,090
Among cisgender women[5]	CAB-LA dominant[b]
Duration of HIV risk	
2 years	$40,432
10 years	$83,206

[a] Base-case analysis compared CAB-LA with FTC/TDF for the overall PrEP-eligible population over a 5-year duration of risk. Oral PrEP adherence was taken from the HPTN 083 trial, and CAB-LA persistence was assumed to be 20% greater than oral PrEP persistence.

[b] A dominant scenario means that CAB-LA is less costly and more effective than the selected comparator option.

[1] Mera et al. (2019); [2] Oglesby et al. (2021); [3] Landovitz et al. (2021) and ViiV data on file (2021a); [4] ViiV data on file (2020b); [5] Calculated based on information from Smith et al. (2018), US Census Bureau (2020), and AtlasPlus (2021).

Limitations

The cost-effectiveness model has limitations that should be considered when interpreting the results.

- Some PrEP-eligible population characteristics are not well-documented, but the model used published data and conservative estimates when necessary.
- Base HIV incidence for TGW and cisgender women was assumed or calculated, respectively, based on published data.
- HIV incidence estimates while receiving PrEP were taken from relevant clinical trials, which may not mirror real-world use.
- No utility decrement was applied while receiving PrEP because it was assumed that individuals who choose to receive PrEP view their choice positively.
- The estimate for the years of PrEP-related breakthrough resistance differentiation was based on a somewhat dated study, but it was the most recent available published data.

Conclusions

CAB-LA prevented more primary and secondary HIV-1 infections than daily oral FTC/TDF and yielded fewer QALYs lost.

CAB-LA increased PrEP-related costs, but it also reduced downstream HIV-related costs.

CAB-LA is cost-effective compared with FTC/TDF for individuals at risk of acquiring HIV-1 infection.

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