F/TAF vs F/TDF for PrEP: How Much is "Better" Worth?

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BACKGROUND

- PrEP: a cornerstone of the End the HIV Epidemic (EHE) campaign.
- Since 2012, F/TDF has been the only FDA-approved drug for PrEP.
- In 2019, F/TAF was approved for use in MSM and transgender women.
- The DISCOVER trial found F/TAF non-inferior to F/TDF with less impact on markers of renal and bone safety.
- Generic F/TDF will be available as a less costly PrEP option in 2020.

OBJECTIVE

To estimate the greatest possible clinical benefits and economic savings attributable to F/TAF's improved safety profile and the maximum price payers should be willing to pay for F/TAF over generic F/TDF

INPUT DATA

Table 1. Input parameters

	Value		Source
Cohort Characteristics: 2018 MSM PrEP Users			
Total	123,610		
13-24 years	16,069		1
25-34 years	49,442		
35-44 years	28,429		
45-54 years	19,777		
>55 years	9,888		
Bone Mineral Density			
Fracture risk on F/TDF, per 10,000 patient-years of use			
	Osteopenia	Hip	Non-hip
13-34 years	7	5	4
35-54 years	25	11	18
>55 years	22	15	15	2
Quality of life, in year of fracture	0.7	0.7	0.7	3
End Stage Renal Disease (ESRD)				
ESRD risk on F/TDF, per 1,000 patient-years				
	ESRD 2	ESRD 3-4		
13-24 years	43	86		
25-34 years	110	220		
35-44 years	254	508		4
45-54 years	467	934		
>55 years	1196	2392		
Quality of life with ESRD, for duration	0.53	0.53		5
Costs (adjusted to 2018 USD)				
Fracture (one time)	$70,400			6
End-Stage Renal Disease (annual)	$92,100-$95,500			4,7
Drug Costs				
Branded F/TAF	$16,600			8
Generic F/TDF (50% discount)	$8,300			Assumption, 9

Sources

1. AIDSVu, 2016 and 2017 data
2. Komatsu et al. *Drug Saf.* 2018
3. Parthan et al. *US Appl Health Econ Health Policy.* 2013.
4. United States Renal Data System, 2018
5. Eckman et al. *Ann Intern Med.* 2018
6. Gu et al. *Clin Orthop Relat Res.* 2014
7. CDC, Chronic Kidney Disease Surveillance System
8. US Department of Veterans Affairs
9. IMS Health, 2015

METHODS

- We used published data to estimate fractures, ESRD cases, quality-adjusted life years (QALYs), costs, and cost-effectiveness of F/TAF.
- We intentionally portrayed the bone and renal safety benefits of F/TAF in the most favorable light possible.
- Using willingness-to-pay thresholds of $50,000, $100,000 and $150,000 / QALY, we projected the maximum justifiable price for F/TAF.
- We estimated the number of people who could be provided PrEP with F/TDF and F/TAF, assuming the entire current US HIV prevention budget of $900.8 million was allocated to PrEP.

Improved renal and bone markers of F/TAF justify a markup of no greater than $370 over generic F/TDF in the US

RESULTS

Table 2. Cumulative 5-year clinical and cost outcomes of F/TAF compared to F/TDF among MSM in the US

	F/TAF Outcomes		F/TDF Outcomes				
Age group (years)	**QALYs**	**Costs, billions (2018$)**	**Excess cases of ESRD**	**Excess fractures**	**QALYs**	**Costs, billions (2018$)**	**ICER** (Δ$/ΔQALYs)
13-24	80,344	1.3	0.2	128	80,305	0.7	16,960,000
25-34	247,210	4.1	2	393	247,090	2.1	16,380,000
35-44	142,150	2.4	5	764	141,910	1.2	4,681,200
45-54	98,884	1.6	7	568	98,698	0.9	4,163,500
55+	49,442	0.8	11	250	49,341	0.4	3,836,700
Total	**618,030**	**10.3**	**25**	**2,101**	**617,340**	**5.3**	**7,201,200**

- Switching all patients to F/TAF-based PrEP will increase total expenditures by $5.0 billion over a 5-year horizon.
- The ICER of switching all PrEP users to F/TAF exceeds $7 million/QALY.
- The ICER of switching all PrEP users >55 years of age is lower, but exceeds $3 million/QALY.

RESULTS

Table 3. Permissible cost of F/TAF

	Willingness to Pay Threshold		
Annual F/TDF cost (% price reduction)	**<$50,000 /QALY**	**<$100,000 /QALY**	**<$150,000 /QALY**
Total Population			
$8,300 (50%)	$8,610	$8,670	$8,730
$8,300 (75%)	$4,460	$4,520	$4,580
$8,300 (90%)	$1,970	$2,030	$2,090
Population >55 years			
$8,300 (50%)	$8,870	$8,970	$9,070
$8,300 (75%)	$4,720	$4,820	$4,920
$8,300 (90%)	$2,230	$2,330	$2,430

- At a willingness-to-pay threshold of $100,000/QALY, the maximum justifiable price markup of F/TAF over F/TDF is $370 in the total population and $670 in the population >55 years of age.

Coverage of PrEP under the $900.8 million US HIV prevention budget

- At the current price of F/TAF ($16,000) and a fixed US HIV prevention budget of $900.8 million, F/TAF would allow for no more than 54,300 people to receive PrEP, 11% of the estimated 492,000 MSM.
- This coverage level could be doubled (quadrupled), by switching to a generic F/TDF alternative priced at a 50% (75%) discount to the branded option.

LIMITATIONS

- We "tipped the scales" in favor of F/TAF. Accounting for the potential benefits of F/TDF – including lipid profiles, weight gain, and ASCVD risk from F/TAF, would further reduce the justifiable premium for F/TAF.
- Our findings are not focused on other PrEP-using populations, such as cis- or transgender women and people who inject drugs.

CONCLUSIONS

- As currently priced, F/TAF will not be cost-effective in the US compared to generic F/TDF, even in populations at highest risk for F/TDF adverse events.
- The imminent availability of generic F/TDF represents an extraordinary opportunity to expand PrEP coverage among the most price-sensitive members of the HIV at-risk population.
- If branded F/TAF drives out generic F/TDF and inhibits uptake, overall rates of PrEP coverage could fall and F/TAF could end up causing more avoidable HIV transmission than it prevents.