

Toward Medicaid Prescription Drug Cost Savings in New York State

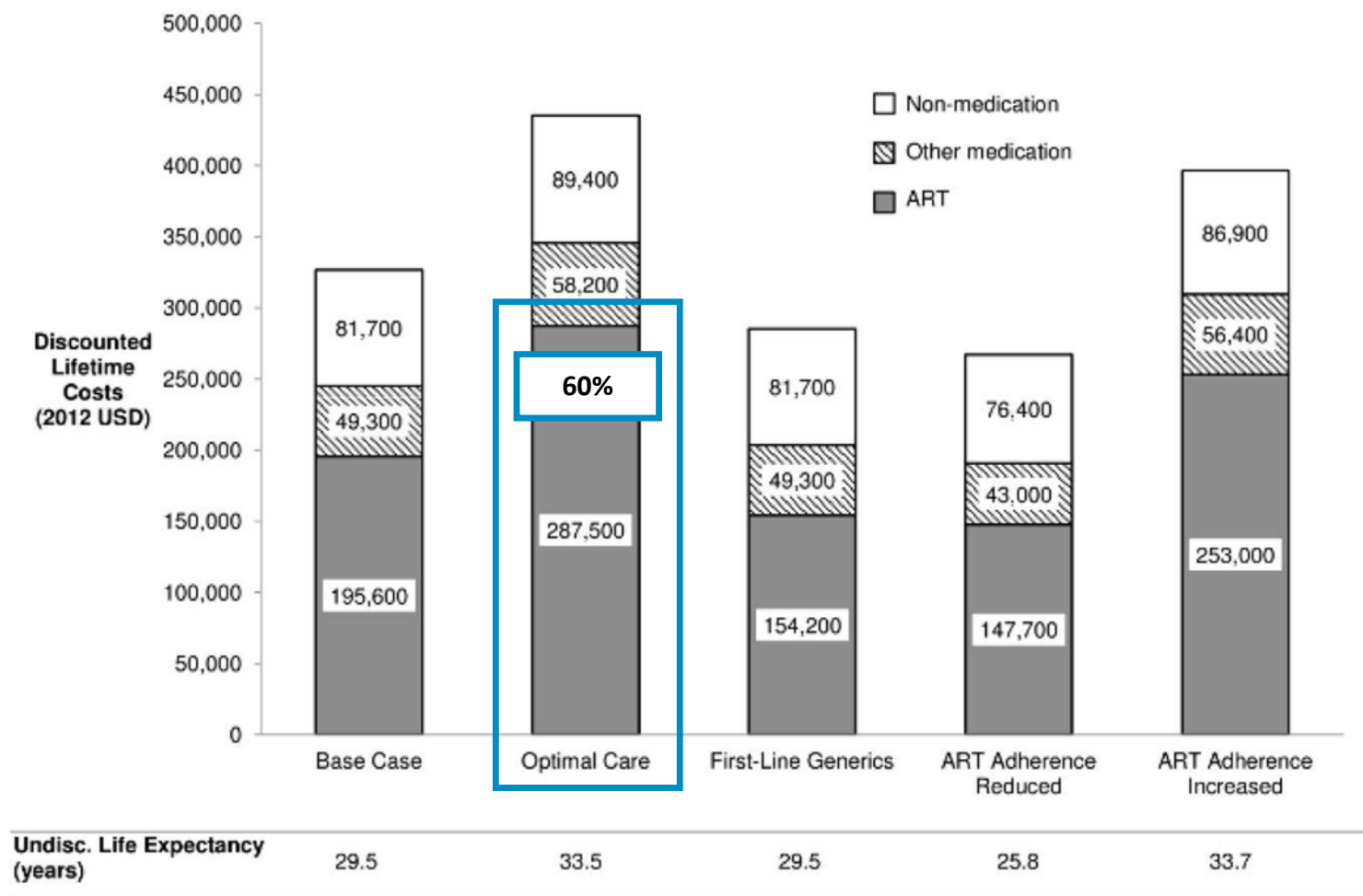
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I have no conflicts of interest

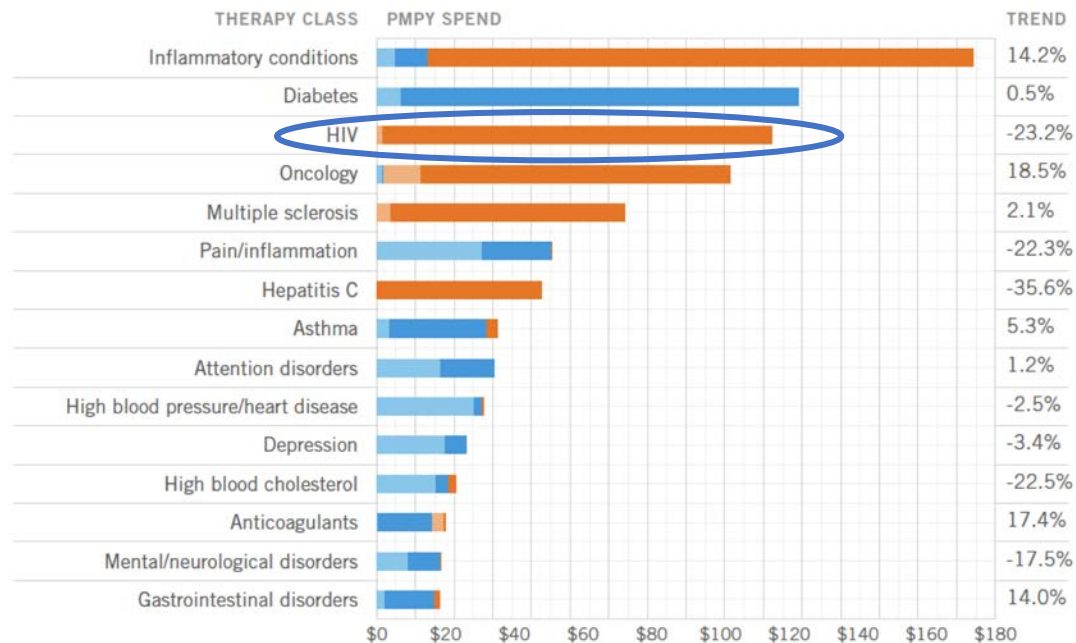
HIV Care Costs



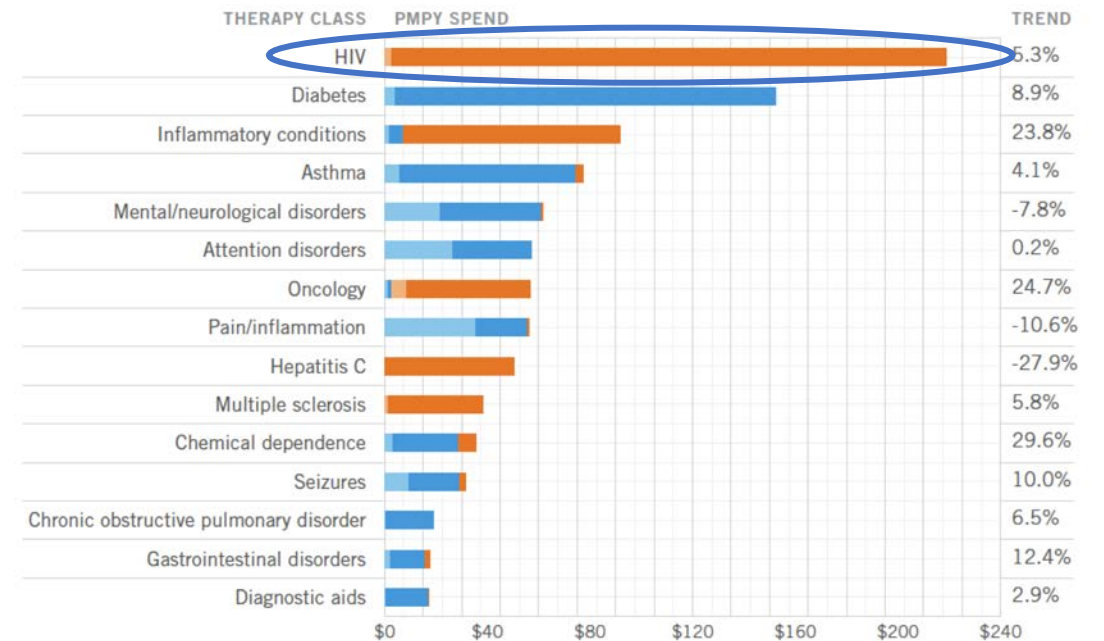
Schackman BR, Fleishman JA, AE, Berkowitz BK, Moore RD, Walensky RP, Becker JE, Voss C, Paltiel AD, Weinstein MC, Freedberg KA, Gebo KA, Losina E. The lifetime medical cost savings from preventing HIV in the United States. *Med Care*. 2015 Apr;53(4):293-301.

Per-Person Spending (2017)

ACA Marketplace Plans



Medicaid



Express Scripts. 2017 drug trend report. <http://lab.express-scripts.com/lab/drug-trend-report/~media/2b56ec26c9a04ec2bcca0e9bf1ea8ff1.ashx>

Lower-cost ARVs

- Branded Drugs: No Patent or FDA Exclusivity Protections
 - Symfi, Symfi Lo, Cimduo
 - Potential generic competition, not interchangeable by pharmacies, copay assistance
- Generic Drugs
 - abacavir, abacavir/3TC, atazanavir, didanosine, 3TC, nevirapine, ritonavir, stavudine, TDF
 - Six-month exclusivity periods possible; the more competition, the lower the price; no copay assistance
- Branded Drugs: Patent and FDA Exclusivity Protections
 - Delstrigo, dolutegravir/3TC (2019)
 - Includes patented and off-patent drugs; lower(-ish) launch prices; copay assistance likely

Recommended Initial Regimens for Most People with HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use.

INSTI + 2 NRTIs:

- BIC/TAF/FTC (AI)
- DTG/**ABC/3TC**^a (AI)—if HLA-B*5701 negative
- DTG + **tenofovir**^b/**FTC**^a (AI for both TAF/FTC and TDF/FTC)
- RAL^c + **tenofovir**^b/**FTC**^a (AI for TDF/FTC, All for TAF/FTC)

EFV/TDF + FTC or **3TC** listed as a Recommended Initial Regimen in Certain Clinical Situations

^a **3TC may be substituted for FTC, or vice versa.** ABC/3TC, TDF/3TC, TDF/FTC, and TAF/FTC are available as coformulated, two-NRTI tablets, and they are also available as part of various STRs. Cost, access, and availability of STR formulations are among the factors to consider when choosing between 3TC and FTC.

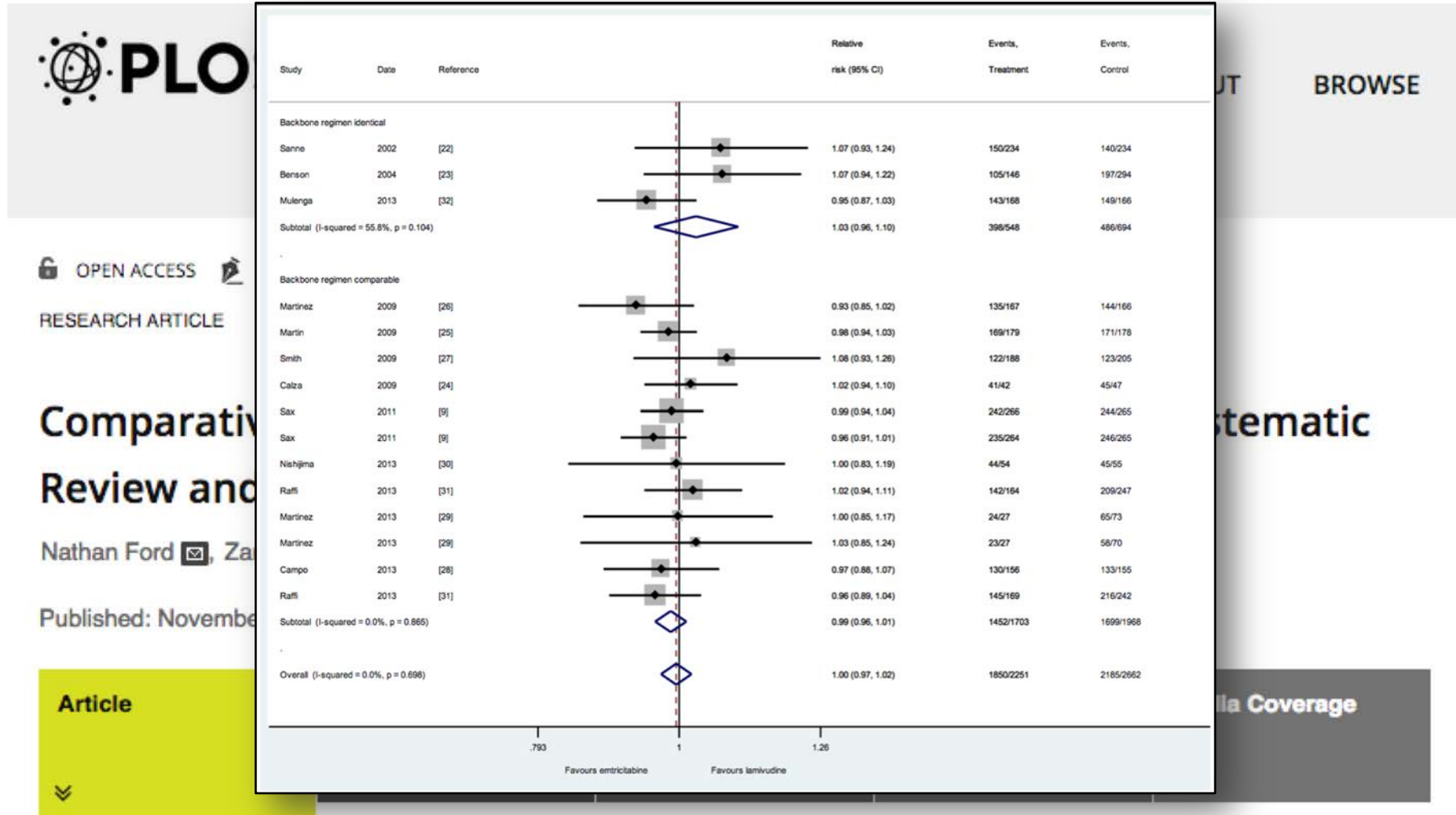
^b TAF and TDF are two forms of tenofovir approved by the FDA. TAF has fewer bone and kidney toxicities than TDF, while TDF is associated with lower lipid levels. **Safety, cost, and access are among the factors to consider when choosing between these drugs.**

The NYS DURB should fully evaluate the suitability of Cimduo for inclusion on the PDL, with Truvada reclassified as non-preferred, for all HIV-positive Medicaid clients currently receiving Truvada or opting to initiate ARV therapy with a Truvada-inclusive regimen (STR)

TDF/FTC (Truvada) & TDF/3TC (Cimduo)

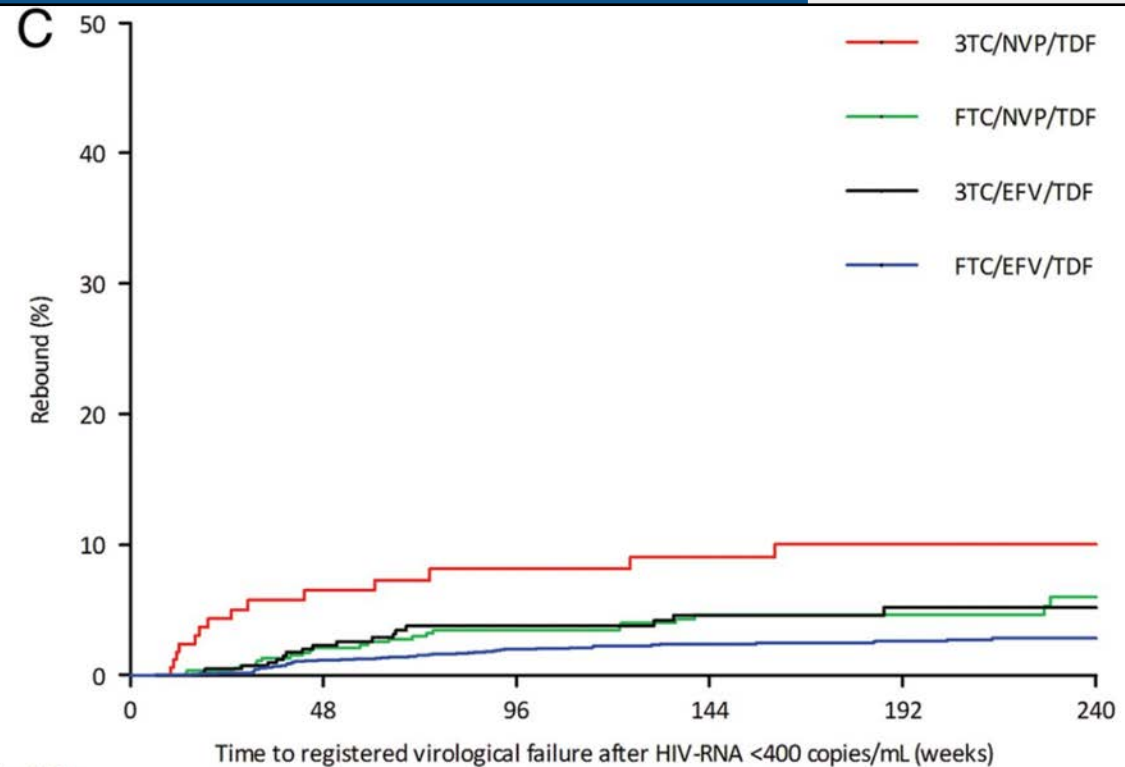
- TDF, with either 3TC or FTC, has been studied in combination with DOR, EFV, RPV, several boosted PIs, EVG/c, RAL, and DTG in randomized clinical trials
- FTC and 3TC largely considered interchangeable by World Health Organization, HHS ARV Guidelines panel, and other best-practice guidelines
- TDF/FTC current price (WAC): \$1,675/month
 - Launched at \$650/month (157% increase)
- TDF/3TC launch price: \$1,005 (~40% below current Truvada price)

FTC vs. 3TC



TDF/FTC vs. TDF/3TC

Clinical



Patients at risk	0	48	96	144	192	240
3TC/NVP/TDF	193	123	106	98	83	68
FTC/NVP/TDF	669	485	392	293	205	107
3TC/EFV/TDF	535	361	272	212	158	116
FTC/EFV/TDF	3343	2631	2050	1546	1056	620

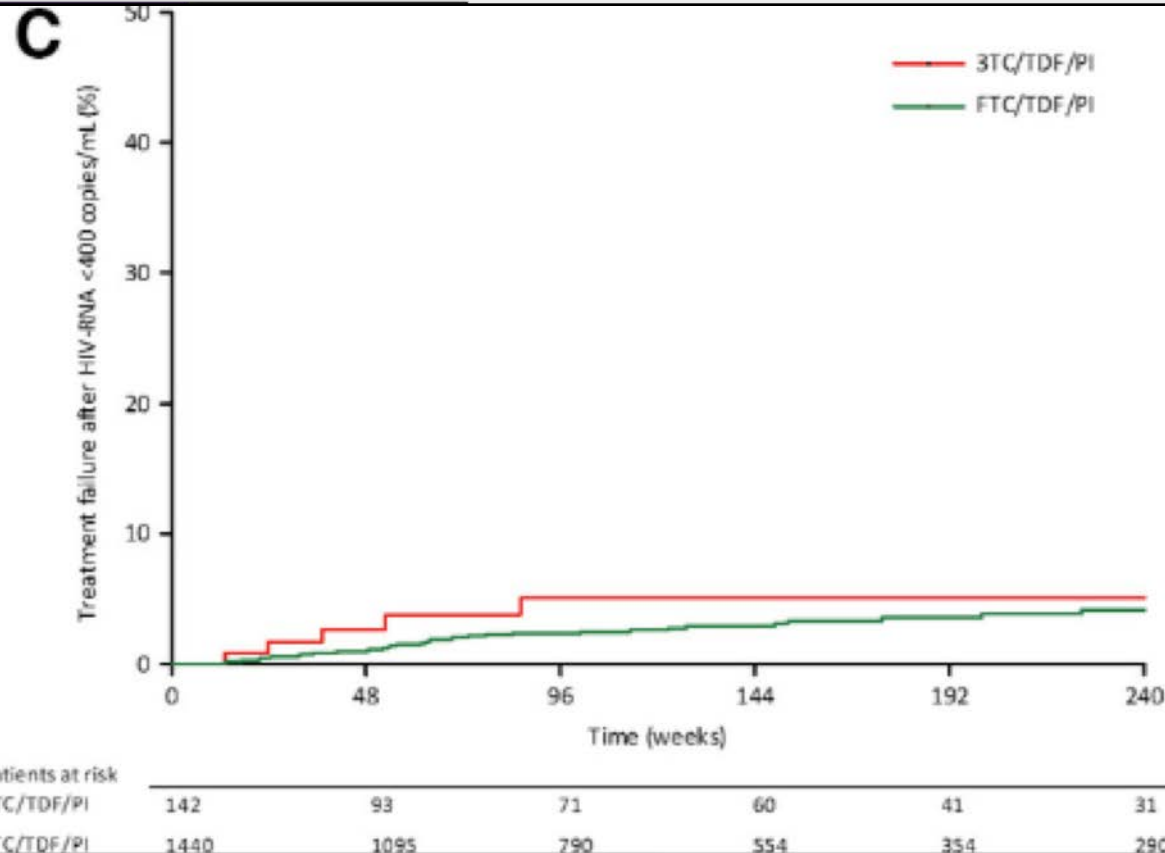
HIV MED

Original Research

Virological combined naïve HIV-1 Evaluation

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- DURB recommendation *does not* include preference for TDF/3TC over TAF/FTC (or other TAF-inclusive regimens)
 - That said, the clinical value of TAF over TDF – particularly when used in regimens that do not contain a boosting agent – remains uncertain¹

¹Hill A, Hughes SL, Gotham D, Pozniak AL. Tenofovir alafenamide versus tenofovir disoproxil fumarate: is there a true difference in efficacy and safety? J Virus Erad. 2018 Apr 1;4(2):72-79

The NYS DURB should fully evaluate the suitability of Symfi and/or Symfi Lo for inclusion on the Preferred Drug List (PDL), with Atripla reclassified as non-preferred, for all HIV-positive Medicaid clients currently receiving Atripla or opting to initiate ARV therapy with an efavirenz-inclusive single-tablet regimen (STR)

EFV/TDF/FTC and EFV/TDF/3TC

- Several commercial payers have dropped Atripla from their formularies, or now consider Atripla non-preferred
 - United Healthcare
 - Blue Cross/Blue Shield
 - ExpressScripts
- Atripla current price: \$2,724/month
 - Launched at \$1,150/month (136% price increase)
- Symfi/Symfo Lo current price: \$1,634 (~40% below current Atripla price)

EFV(600)/TDF/FTC vs. EFV(400)/TDF/FTC: Efficacy

THE LANCET

ARTICLES | [VOLUME 383, ISSUE 9927, P1474-1482, APRIL 26, 2014](#)

Efficacy of 400 mg efavirenz versus standard 600 mg dose in HIV-infected, antiretroviral-naïve adults (ENCORE1): a randomised, double-blind, placebo-controlled, non-inferiority trial

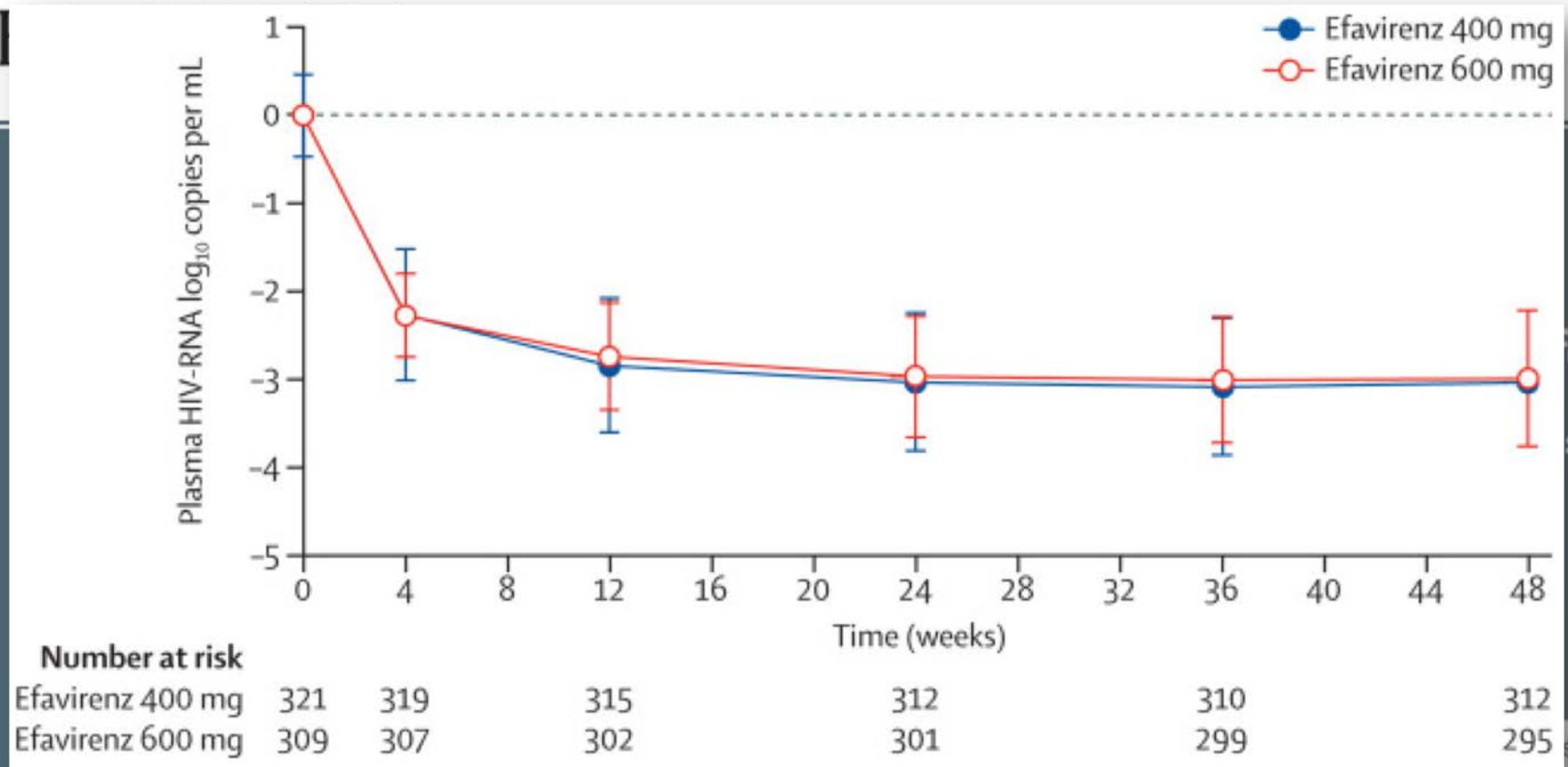
ENCORE1 Study Group [†] • [Show footnotes](#)

Published: February 10, 2014 • DOI: [https://doi.org/10.1016/S0140-6736\(13\)62187-X](https://doi.org/10.1016/S0140-6736(13)62187-X) •

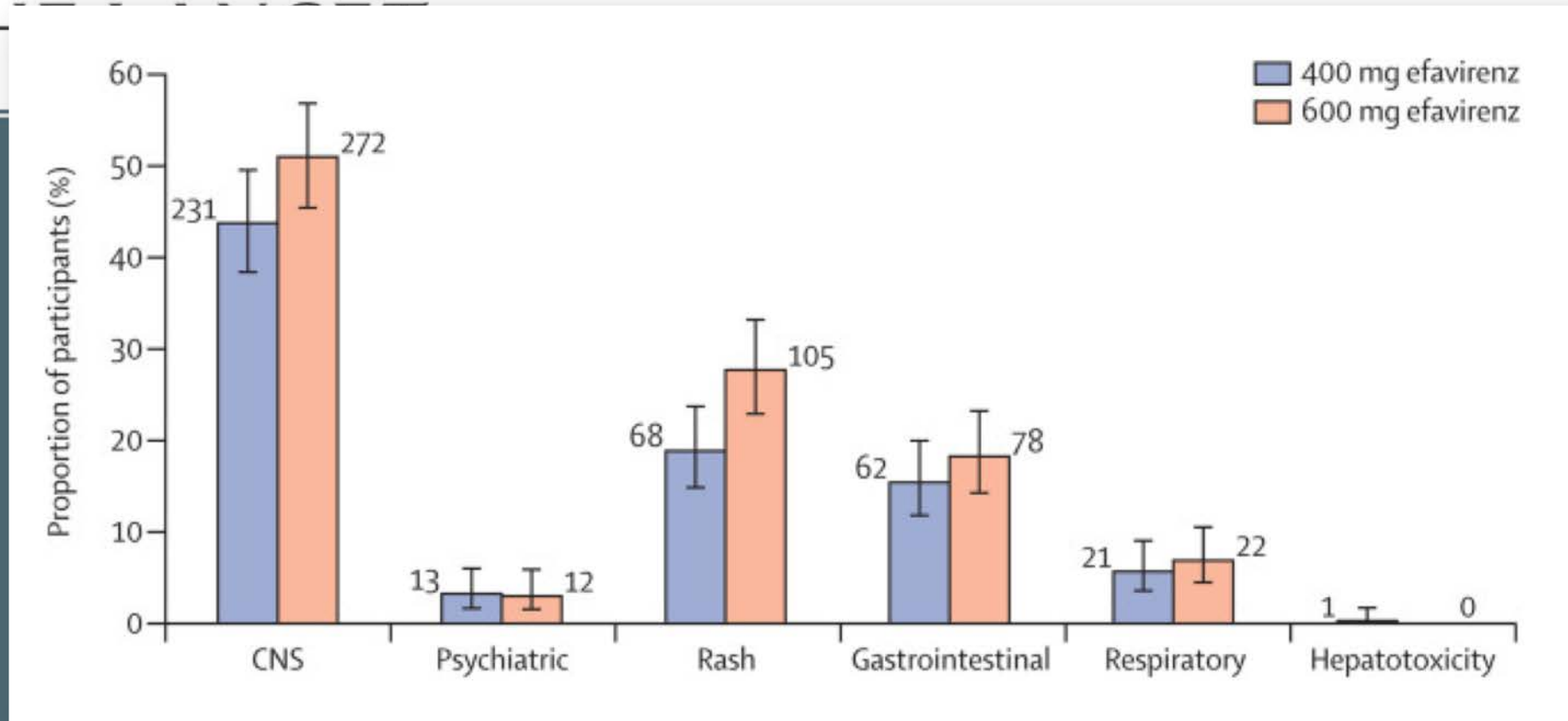


EFV(600)/TDF/FTC vs. EFV(400)/TDF/FTC: Efficacy

THI



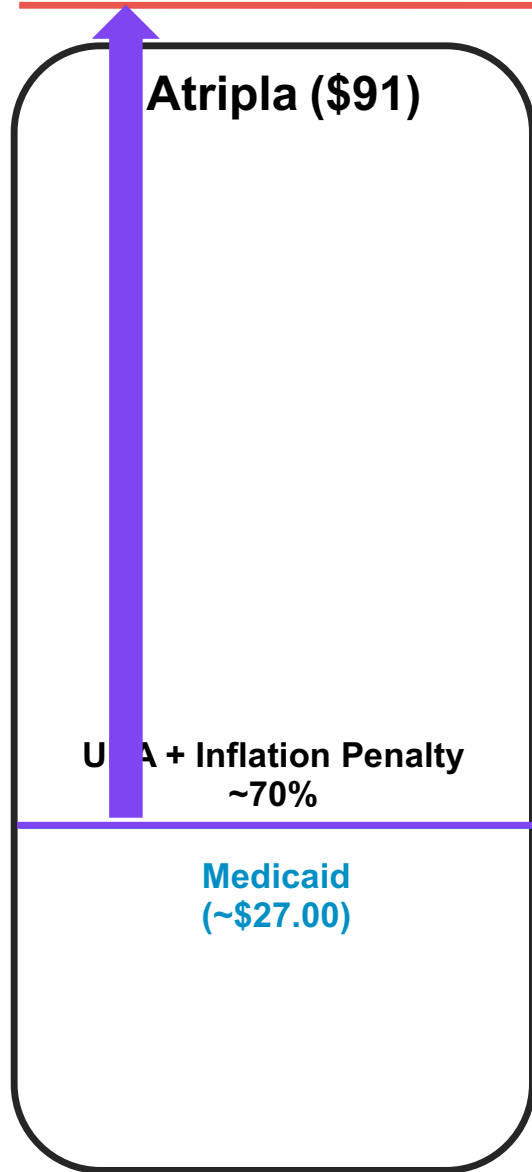
EFV(600)/TDF/FTC vs. EFV(400)/TDF/FTC: Efficacy



-
- DURB recommendation *does not* include preference for Symfi or Symfi Lo over any other multi-tablet or single-tablet regimens

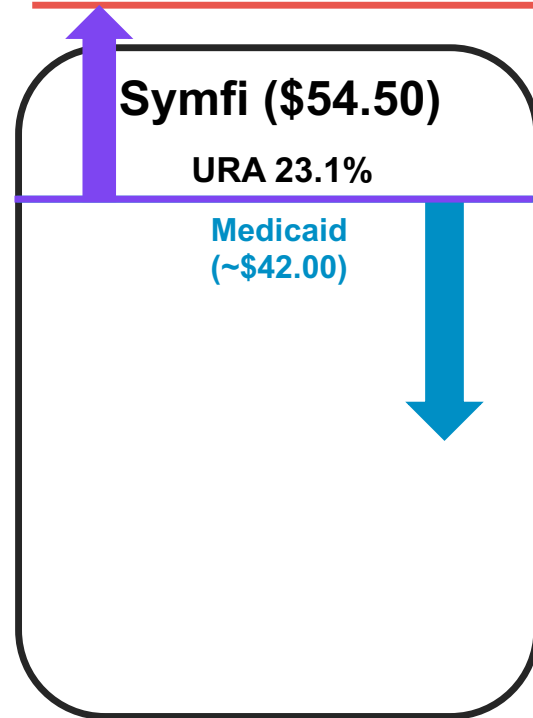
[These recommendations are] contingent on voluntary rebates, beyond the 23.1% URA that currently applies to [Symfi/Symfi Lo/Cimduo], to achieve cost savings that exceed those associated with [Atripla and Truvada's] statutorily required URA and CPI penalties, plus any negotiated supplemental rebates

Commercial Plans

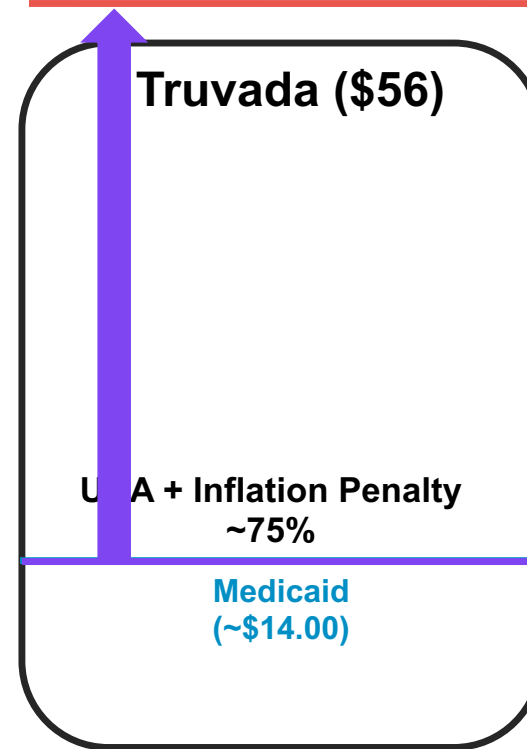


Beyond Benchmark Prices

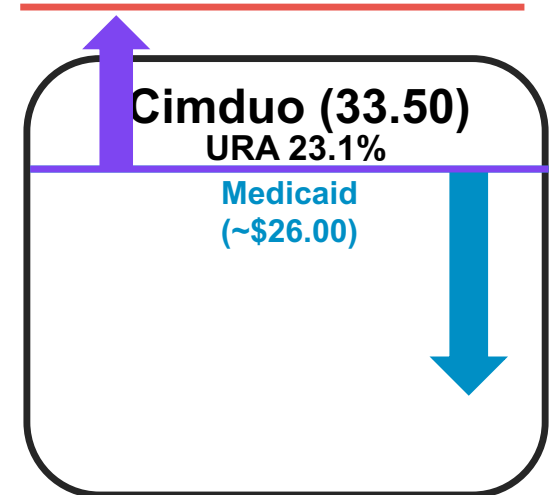
Commercial Plans



Commercial Plans



Commercial Plans



Potential NYS Medicaid Cost Savings: Atripla

Atripla Q1 2018 Data

- Monthly prescriptions (FFS and MCO): 1,904
- Medicaid reimbursement (FFS and MCO): \$4,000,000
- Estimated rebates: \$3,499,000
- Estimated net cost to NYS Medicaid: \$1,500,000

Estimated Symfi/Symfi Lo

- Monthly prescriptions (FFS and MCO): 1,904
- Medicaid reimbursement (FFS and MCO): \$4,000,000
- Estimated rebates (without voluntary 40%): \$718,672
- Estimated rebates (with URA + voluntary 40% [25% <Atripla]): \$1,100,000
- Estimated net cost to NYS Medicaid: \$1,100,000

Monthly cost savings: \$400,000
Annual cost savings: \$4,800,000

Potential NYS Medicaid Cost Savings: Truvada

Truvada Q1 2018 Data

- Monthly prescriptions (FFS and MCO): 6,739 (~ on PrEP¹)
- Medicaid reimbursement (MCO): \$10,779
- Estimated rebates: \$7,300,000
- Estimated net cost to NYS Medicaid (total): \$4,200,000
- Estimated net cost to NYS Medicaid (*Tx only*): \$460,000 monthly

Estimated Cimduo

- Monthly prescriptions (FFS and MCO): 6,739 (~ on PrEP¹)
- Medicaid reimbursement (FFS and MCO): \$10,779
- Estimated rebates (without voluntary rebating): \$171,794
- Estimated rebates (with URA + voluntary 46% [25% <Truvada]): \$1,038,206
- Estimated net cost to NYS Medicaid: \$233,000 monthly

Monthly cost savings: \$227,000

Annual cost savings: \$2,724,000

¹Ending the Epidemic Community Metrics Meeting. 2018 October 29 conference call minutes.

Summary

- TDF/FTC and TDF/3TC are largely considered interchangeable
- EFV 600/TDF/FTC and EFV 600/TDF/3TC are largely considered interchangeable; Data from a randomized clinical trial indicate EFV 400/TDF/FTC to be non-inferior to EFV 600/TDF/FTC, with potential safety advantages
- Cost savings to NYS Medicaid FFS and MCOs will depend on substantial voluntary rebates on Symfi, Symfi Lo, and Cimduo
- Rx cost (~\$6.5 million) savings have societal benefit – is there an opportunity to reinvest savings to support NYS EtE outcomes?

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