Budget Impact of the Introduction of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir, the First Integrase Inhibitor-Based Single-Tablet Antiretroviral Regimen for HIV Treatment, to US Third-Party Payers

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BACKGROUND

- The elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF) regimen for the treatment of human immunodeficiency virus (HIV) infection is the first integrase strand transfer inhibitor-based single-tablet regimen (STR) administered once daily.
- In head-to-head clinical trials against regimens listed as preferred in the United States (US) Department of Health and Human Services (DHHS) guidelines, EVG/COBI/FTC/TDF has shown statistically noninferior efficacy to efavirenz (EFV)/FTC/TDF and atazanavir (ATV)+ritonavir (RTV)+FTC/TDF. Additionally, EVG/COBI/FTC/TDF has shown statistically fewer adverse events (e.g., central nervous system effects, rash, and fasting total cholesterol and low density lipoprotein levels) than the DHHS-preferred regimens.
- Adherence is considered to be among the most important factors influencing clinical outcomes; regimen complexity and high pill burden can have detrimental effects on adherence.
- STRs are associated with improved medication adherence, better virologic suppression, lower hospitalization rates, and lower health care costs.[1]
- Utilization of EVG/COBI/FTC/TDF is expected to increase over the next several years, potentially reducing utilization of more expensive boosted protease inhibitor (PI/r)-based regimens.

OBJECTIVE

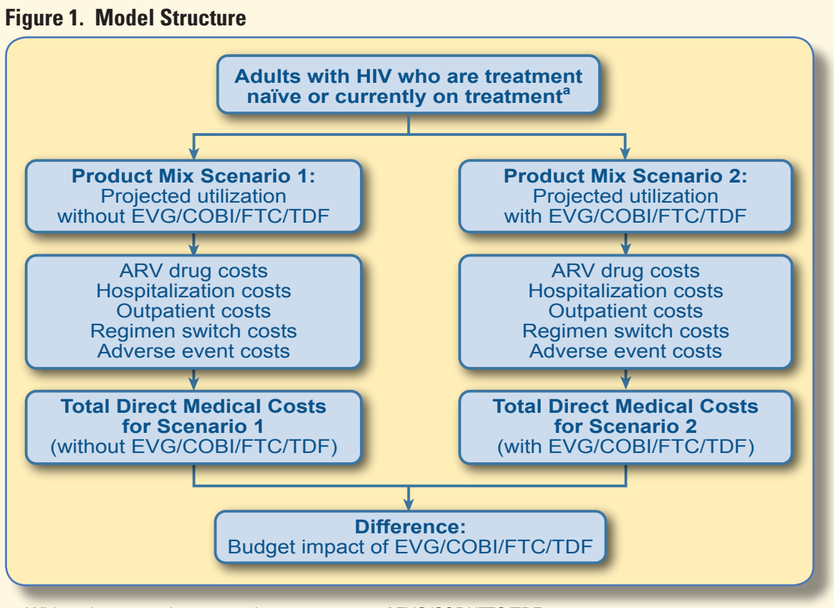
- To estimate the budget and health impact for a US health care plan of increased use of EVG/COBI/FTC/TDF in adults with HIV who are treatment naïve or currently on treatment with no known resistance to EVG/COBI/FTC/TDF.

METHODS

Model Structure

- The population modeled included adults with HIV infection who were treatment naïve or currently on treatment with no known resistance to EVG/COBI/FTC/TDF.
- Each year, individuals currently on treatment could switch therapy, if eligible; treatment-naïve individuals could initiate therapy.
- Treatment regimens in the model included EVG/COBI/FTC/TDF and the six most commonly prescribed antiretroviral (ARV) regimens for adults with HIV who are treatment naïve or currently on treatment with no known resistance to EVG/COBI/FTC/TDF[2]:
  - EFV/FTC/TDF
  - Raltegravir (RAL)+FTC/TDF
  - Atazanavir (ATV)+RTV+FTC/TDF
  - Darunavir (DRV)+RTV+FTC/TDF
  - Lopinavir (LPV)/RTV+FTC/TDF
  - Rilpivirine (RPV)/FTC/TDF
- The model estimated the impact on payer budgets by comparing total direct health care costs associated with HIV management in two scenarios:
  - Scenario 1: projected ARV utilization without EVG/COBI/FTC/TDF
  - Scenario 2: projected ARV utilization with expected uptake of EVG/COBI/FTC/TDF
- Total direct medical costs in the model comprised ARV drug costs, hospitalization costs, outpatient HIV management costs, regimen switching costs, and adverse event costs.
- Figure 1 presents a schematic of the model structure. The model first estimated total direct medical costs separately for each treatment regimen. Total direct medical costs for each scenario were then calculated by weighting these regimen-based totals by the ARV utilization data and multiplying the result by the size of the modeled population. The budget impact was the difference in the costs between the two scenarios.
- Following standard methodology for budget-impact analyses, the budget was calculated annually and cumulatively over a 3-year period without discounting. All costs are presented in 2012/2013 US dollars and were inflated from prior years, where necessary.[3] The perspective of the analysis was that of a third-party commercial or government payer.

Figure 1. Model Structure



[a] With no known resistance to the components of EVG/COBI/FTC/TDF.

Input Parameters

- The size of the modeled population was estimated from published HIV epidemiology studies and publicly available data.
- EVG/COBI/FTC/TDF utilization was projected to be 5% (year 1), 8% (year 2), and 12% (year 3). Utilization of comparator regimens was estimated from a recent chart audit analysis, and EVG/COBI/FTC/TDF utilization was projected to come from PI/r-based regimens in relative proportion to each regimen's current utilization.
- ARV drug costs for each regimen were calculated from indicated daily dosing and drug unit costs (wholesale acquisition costs) (Table 1).[4]
- Annual rates of hospitalization (7.4% for individuals receiving an STR; 8.4% for all others) were calculated from the results of a retrospective database analysis among managed care enrollees.[1]
- The average cost of a hospitalization ($20,437) was obtained from an analysis of the HCUPNet database.[5] Annual outpatient management costs ($4,305) were taken from a published resource-use study,[6] and regimen switching costs ($273) were based on an additional physician visit and laboratory tests.[7]
- Adverse event incidence data were taken from published clinical trials for all comparator regimens; management costs were taken from published economic models or based on appropriate treatment algorithms.

Table 1. Daily ARV Drug Costs and Pill Count

ARV Regimen	Daily Cost	Pills Per Day
EVG/COBI/FTC/TDF	$78.08	1
EFV/FTC/TDF	$62.61	1
RAL+FTC/TDF	$76.58	3
ATV+RTV+FTC/TDF	$85.63	3
DRV+RTV+FTC/TDF	$85.71	3
LPV/RTV+FTC/TDF	$66.41	5
RPV/FTC/TDF	$64.55	1
Other regimens[a]	$64.83	At least 2

[a] Average daily cost of other ARV regimens recommended as "alternative" or "acceptable" in the US treatment guidelines for treatment-naïve patients.[2]

RESULTS

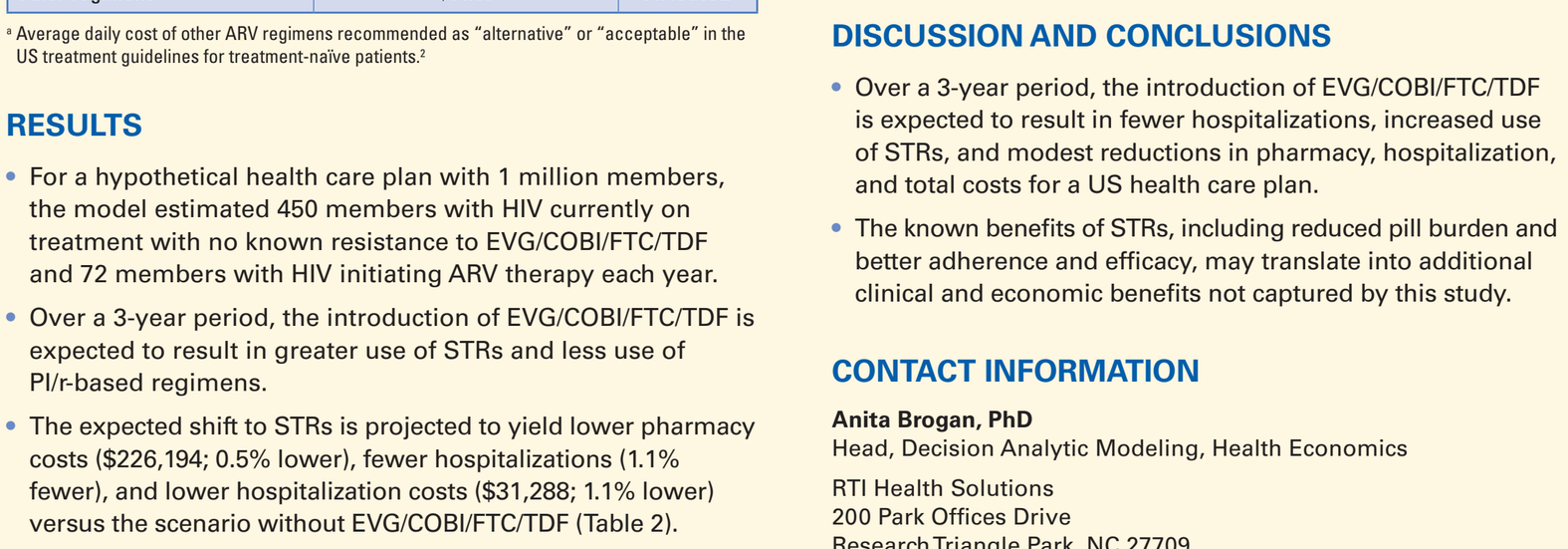
- For a hypothetical health care plan with 1 million members, the model estimated 450 members with HIV currently on treatment with no known resistance to EVG/COBI/FTC/TDF and 72 members with HIV initiating ARV therapy each year.
- Over a 3-year period, the introduction of EVG/COBI/FTC/TDF is expected to result in greater use of STRs and less use of PI/r-based regimens.
- The expected shift to STRs is projected to yield lower pharmacy costs ($226,194; 0.5% lower), fewer hospitalizations (1.1% fewer), and lower hospitalization costs ($31,288; 1.1% lower) versus the scenario without EVG/COBI/FTC/TDF (Table 2).
- Total cost savings over 3 years were estimated at $240,375 (0.4% lower), equivalent to a reduction in per-treated-member annual costs from $32,454 to $32,319 and in per-member-per-month (PMPM) costs from $1.61 to $1.60 (Figure 3).
- PMPM results were insensitive to changes in parameter values.

Table 2. Budget-Impact Results[a]

Year/Outcome	Scenario 1: Projected ARV Utilization Without EVG/COBI/FTC/TDF	Scenario 2: Projected ARV Utilization With EVG/COBI/FTC/TDF	Impact, Incremental (Relative) Difference
Year 1			
Percentage on STR	32.0%	37.0%	5.0% (15.6%)
Total annual cost	$16,933,703	$16,896,102	–$37,601 (–0.2%)
PMPM cost	$1.41	$1.41	$0.00 (–0.2%)
Year 2			
Percentage on STR	32.0%	40.0%	8.0% (25.0%)
Total annual cost	$19,263,922	$19,188,564	–$75,357 (–0.4%)
PMPM cost	$1.61	$1.60	–$0.01 (–0.4%)
Year 3			
Percentage on STR	32.0%	44.0%	12.0% (37.5%)
Total annual cost	$21,594,140	$21,466,723	–$127,417 (–0.6%)
PMPM cost	$1.80	$1.79	–$0.01 (–0.6%)
3-year cumulative			
Percentage on STR	32.0%	44.0%	12.0% (37.5%)
Total cumulative cost	$57,791,765	$57,551,390	–$240,375 (–0.4%)
PMPM cost	$1.61	$1.60	–$0.01 (–0.4%)

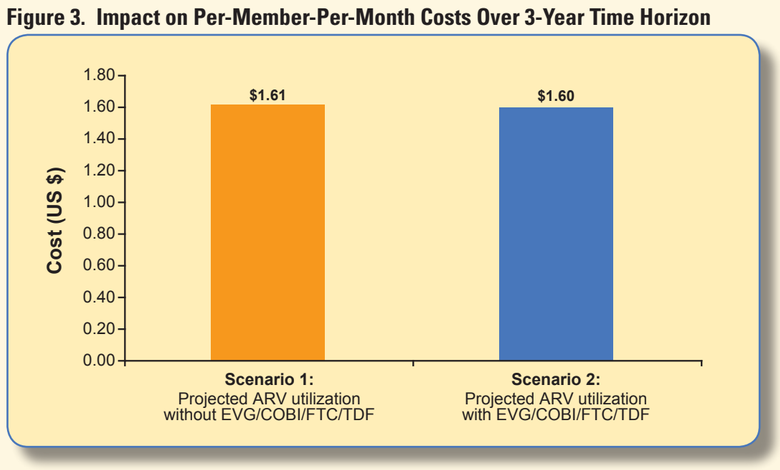
[a] All costs are presented in 2012/2013 US dollars and were inflated from prior years using the medical care component of the US consumer price index, where necessary.[3]

Figure 2. Impact on Annual Costs Per Treated Member



Scenario 1 = projected ARV utilization without EVG/COBI/FTC/TDF; Scenario 2 = projected ARV utilization with EVG/COBI/FTC/TDF.

Figure 3. Impact on Per-Member-Per-Month Costs Over 3-Year Time Horizon



LIMITATIONS

- Clinical trial efficacy data for the comparator regimens were not considered in the budget-impact analysis. The clinical benefits of STRs were accounted for using hospitalization data from a published analysis of commercial claims data.[1]
- This analysis involved the typical limitations of pharmacoeconomic analyses. The time horizon of the model was 3 years. Projections of the impact of EVG/COBI/FTC/TDF on health care budgets over longer time horizons are not available.
- The patient population excluded individuals not eligible for EVG/COBI/FTC/TDF treatment and therefore did not account for all patients on ARV therapy.

DISCUSSION AND CONCLUSIONS

- Over a 3-year period, the introduction of EVG/COBI/FTC/TDF is expected to result in fewer hospitalizations, increased use of STRs, and modest reductions in pharmacy, hospitalization, and total costs for a US health care plan.
- The known benefits of STRs, including reduced pill burden and better adherence and efficacy, may translate into additional clinical and economic benefits not captured by this study.

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REFERENCES

1. Sax PE, Meyers JL, Mugavero M, Davis KL. PLoS One. 2012;7(2):e31591.
2. US Department of Health and Human Services (US DHHS): Panel on Antiretroviral Guidelines for Adults and Adolescents. Available at: http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed August 20, 2012.
3. US Department of Labor: Bureau of Labor Statistics (BLS). Medical care component of consumer price index. Available at: http://www.bls.gov/cpi/#tables. Accessed August 20, 2012.
4. Red Book Online. 2013. Available at: http://www.micromedexsolutions.com/home/dispatch. Accessed April 5, 2013.
5. Healthcare Cost and Utilization Project online database (HCUPNet). 2009 data. Available at: http://hcupnet.ahrq.gov/HCUPnet.jsp. Accessed March 26, 2012.
6. Gebo KA, Fleishman JA, Conviser R, Hellinger J, Hellinger FJ, Josephs JS, et al. AIDS. 2010;24(17):2705-15.
7. The Essential Resource-Based Relative Value Scale (RBRVS). Utah: Ingenix, Inc.; 2012.