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Drug Use Evaluation: Human Immunodeficiency Virus (HIV) Antiretrovirals

Research Questions:

1) What antiretroviral therapies (ARVs) are used by Oregon Health Plan (OHP) patients, are the ARVs used recommended by guidelines and what is the relative net cost?
2) What is the prevalence of OHP patients who are treated prophylactically for HIV transmission?
3) What is the level of adherence to ART by OHP patients?
4) What is the prevalence of OHP patients using ARV regimens that are recommended to be always avoided by United States Department of Health and Human Services (HHS)?[1]
5) What is the prevalence of OHP patients meeting fraud and misuse indicators developed by the HHS Office of Inspector General?[2]

Conclusions:

1) There was approximately a 17% increase in the amount paid to pharmacies per member per month and 8% decrease in claim count per 1000 members per month over the calendar year. This trend was driven by increased use of more expensive combination products resulting in fewer claims but higher costs. Complera™ and Stribild™ cost increased about 50% during this time. The most commonly prescribed ARVs are highly recommended or alternative options according to guidelines.[3] The net cost of the most common ARV regimens varied from a low of about $12,410/year to a high of about $32,850/year. Integrase strand transfer inhibitor (INSTI) therapies are some of the least expensive and have fewer potential drug interactions whereas protease inhibitor (PI) based therapies are some of the more expensive with more potential drug interactions.
2) There is rare use of HIV transmission prophylaxis at this time. Only 12 patients (2.1%) met the definition of post-exposure ARV and 4 patients (0.7%) met the definition of pre-exposure ARV.
3) Adherence to ARV remains a primary concern as just 59.5% of patients were more than 90% adherent to one or more of their ARV drugs. One combination product is significantly more expensive than other competing combination products. Identifying this poor value to prescribers could both improve OHP cost structure while maintaining access to multiple combination products to improve adherence.
4) No OHP patients were using ARVs that are recommended to avoid.
5) Using HHS Office of Inspector General devised criteria; there is little indication of fraud or abuse of ARV drugs in the FFS program. Three patients met the excessive dose indicator but service dates indicate lower doses were likely used by the patient. There were no patients accessing excessive numbers of pharmacies or prescribers. Four patients (0.7%) had exactly 480 “Days Supply” of several drugs each during the year.

Recommendations:

1) Work with established, high Medicaid volume HIV clinics to try to identify ARV regimens with broad tolerability and high viral response rates in most patients and that have favorable or equivalent comparative price (preferred) and try to identify ARV regimens with common tolerability problems or lower viral response rates in most patients and with an unfavorable comparative price (non-preferred).
2) Work with established, high Medicaid volume HIV clinics to determine the best way to educate prescribers of least and best value drugs.
3) Work with established, high Medicaid volume HIV clinics to determine opportunities to collaborate and assist with improving adherence to antiretroviral therapy.

Background:

In Oregon, the prevalence of HIV in 2013 was 5.0 per 100,000 persons (9.2 per 100,000 in men and 0.8 per 100,000 in women).[4] The prevalence was highest for Hispanic men (14.8 per 100,000) and black men (12.3 per 100,000).[4] Oregon counties with HIV rates above the state average included Multnomah (13.4), Polk (10.4), Malheur (6.6) and Washington (5.8) counties.[4] The OHP fee-for-service (FFS) program spent about $500,000 (net of rebate) in the first quarter of 2015 on ARV. The HIV ARV drug class ranks first among the non-mental health carve-out classes for the FFS program and is the highest net cost drug class for coordinating care organizations ($2.5 million). There are 36 unique drugs currently marketed as ARV (Appendix 1). Branded combination drugs currently dominate market share (>50% by net cost) for the entire OHP. Generic formulations are emerging: 4 nucleoside reverse transcriptase inhibitors (NRTIs) and 2 NRTI combination products are now available.

Antiretroviral therapy is recommended for all patients with confirmed HIV infection.[5] An optimal ARV regimen for a treatment-naïve persons consists of 2 NRTIs in combination with a third drug from one of 3 drug classes: an non-nucleoside/nucleotide reverse transcriptase inhibitor (NNRTI), a boosted PI, or an INSTI.[3] A more detailed presentation of particular ARV options is included in the accompanying HIV Antiretroviral Class Review.[6]

The Centers for Disease Control and Prevention (CDC) also recommends pre-exposure prophylaxis or PrEP (specifically Truvada™) as one option for HIV prevention.[7] However, the recommendations also include the caution that: "When PrEP is prescribed, clinicians should provide access, directly or by facilitated referral, to proven effective risk-reduction services. Because high medication adherence is critical to PrEP efficacy but was not uniformly achieved by trial participants, patients should be encouraged and enabled to use PrEP in combination with other effective prevention methods." [7] The CDC suggests to consider prescribing no more than 90-day supply which can be refilled after confirmatory negative HIV test, that the use for coitally timed or other noncontinuous daily use is not recommended and that patients should be seen in routine follow-up to assess HIV status, adverse effects, change in risk behaviors, adherence and social support.[7]

Non-adherence to ARV can negatively impact viral response and can lead to drug resistance.[8] It is documented that patients that have less than 95% adherence have higher rates of viral response failure.[9,10] However, these studies do not reflect the newer ARVs. Pill burden, drug adverse events and complex psycho-social situations can all reduce adherence.[8] The HHS guidelines also note that prior authorization programs promoting use of generic drugs may reduce drug costs but can lead to increased pill burden and lower adherence rates.[8] In response, new formulations containing 3 or 4 antiretroviral drugs have been developed to address potential pill burden.

The HHS Office of Inspector General published an audit of ARV drug use in Medicare Part D patients in August 2014.[2] The audit found 1,578 patients with questionable ARV utilization patterns in 2012[2] including several combinations the HHS guidelines identified as those to always avoid in order to prevent adverse events and resistance development.[1] The audit does not report the total number of Part D patients receiving ARV in 2012 but, the number of patients associated with the most common drug combinations were 72,183 patients.[2] The audit created 6 criteria of questionable use: 1) no record of HIV or HIV indication (n=888); 2) dose exceeding 2-times the recommended dose (n=226); 3) supply exceeding 480 days in the calendar year (n=206); 4) persons accessing more than 6 pharmacies (n=213); 5) persons accessing more than 6 prescribers (n=179); and 6) concurrent use of contraindicated drugs for more than 60 days (n=10).[2] Medicare Part D paid $2.8 billion for HIV drugs and $32 million for questionable use in 2012.[2] The Office of Inspector General recommended expansion of drug utilization review programs, expansion of fraud, waste and abuse monitoring and expansion of beneficiary lock-in programs, among other recommendations.[2]

Methods: All patients with a paid FFS drug claim for an ARV drug in Appendix 1 during the 2014 calendar year were included. Patients with claims for only lamivudine or tenofovir (hierarchical ingredient code list sequence number (HSN) = 010215 OR 022937) in 2014 and no other FFS or encounter claims for ARV drugs from January 1, 2013 to March 31, 2015 were excluded as this indicates hepatitis B treatment in the absence of an HIV diagnosis. Patients with Medicare Part D coverage (BMM or BMD) and patients with less than 274 days (75%) eligible (FFS or CCO combined) during the 2014 calendar year were also excluded as the claims history for these patients is incomplete. For the remaining patients, all encounter and FFS claims from January 1, 2013 to March 31, 2015 were queried for medical and drug history. The

“HIV Population” includes all patients with a FFS claim for an ARV drug in 2014. The “Study Population” is a subset of the HIV Population that also met the 75% eligibility requirement and did not have Part D coverage.
Gross drug cost and utilization trends for the entire HIV Population were calculated using pharmacy reimbursed costs (excluding confidential rebates) and claim counts for ARV drugs per eligible member per month from both FFS and encounter drug claims. Total number of OHP eligible persons, including Part D patients, was used as the denominator to allow similar comparison to the other drug utilization evaluations previously reviewed by the Pharmacy and Therapeutics Committee.

A snap shot of the most current ARV therapy for each patient in the Study Population was identified by using the last ARV claim end date in 2014 (claim end date = claim dispense date + “Days Supply”). Looking back 60 days from the end date, any ARV drug initiated or with active “Days Supply” from a previous fill within the 60-day period was considered part of the patient’s current ARV therapy for 2014. Unique final ARV regimens were identified and the number of patients for each unique regimen was counted. Drug cost was calculated using the average net price per day of each agent in the regimen; cost was not based on actual paid claims.

Post-exposure prophylaxis was quantified by identifying patients with claims for HSN 026515 (emtricitabine/tenofovir) plus HSN 035072 (raltegravir) within 5 days of each other, with less than 35 “Days Supply” for each claim and with no other claim for those two HSNs in the 90 days before or after. Pre-exposure prophylaxis was quantified by identifying patients taking no other ARV drugs except those in HSN 026515 (emtricitabine/tenofovir) in 2014, and who have no HIV ICD9 code (042xx, V08, 079.53 or 795.71) on any medical claim from January 1, 2013 to March 31, 2015.

The length of therapy (“Therapy Length”) in “days” was calculated for each HSN component for each patient using the last claim date in 2014 plus the “Days Supply” entry and subtracting the first claim date in 2014. The medication possession rate (MPR) was calculated for each patient and HSN component using the formula: Total Days Supply / Therapy Length. The combined therapy length for each patient was determined using the last claim date in 2014 of any ARV drug plus the “Days Supply” entry and subtracting the first claim date of any ARV drug in 2014.

Results: Figure 1 displays the overall ARV drug cost and claim count trend per 1000 OHP members per month during 2014. There was approximately a 17% increase in the amount paid to pharmacies per member per month and 8% decrease in claim count per 1000 members per month over the calendar year.

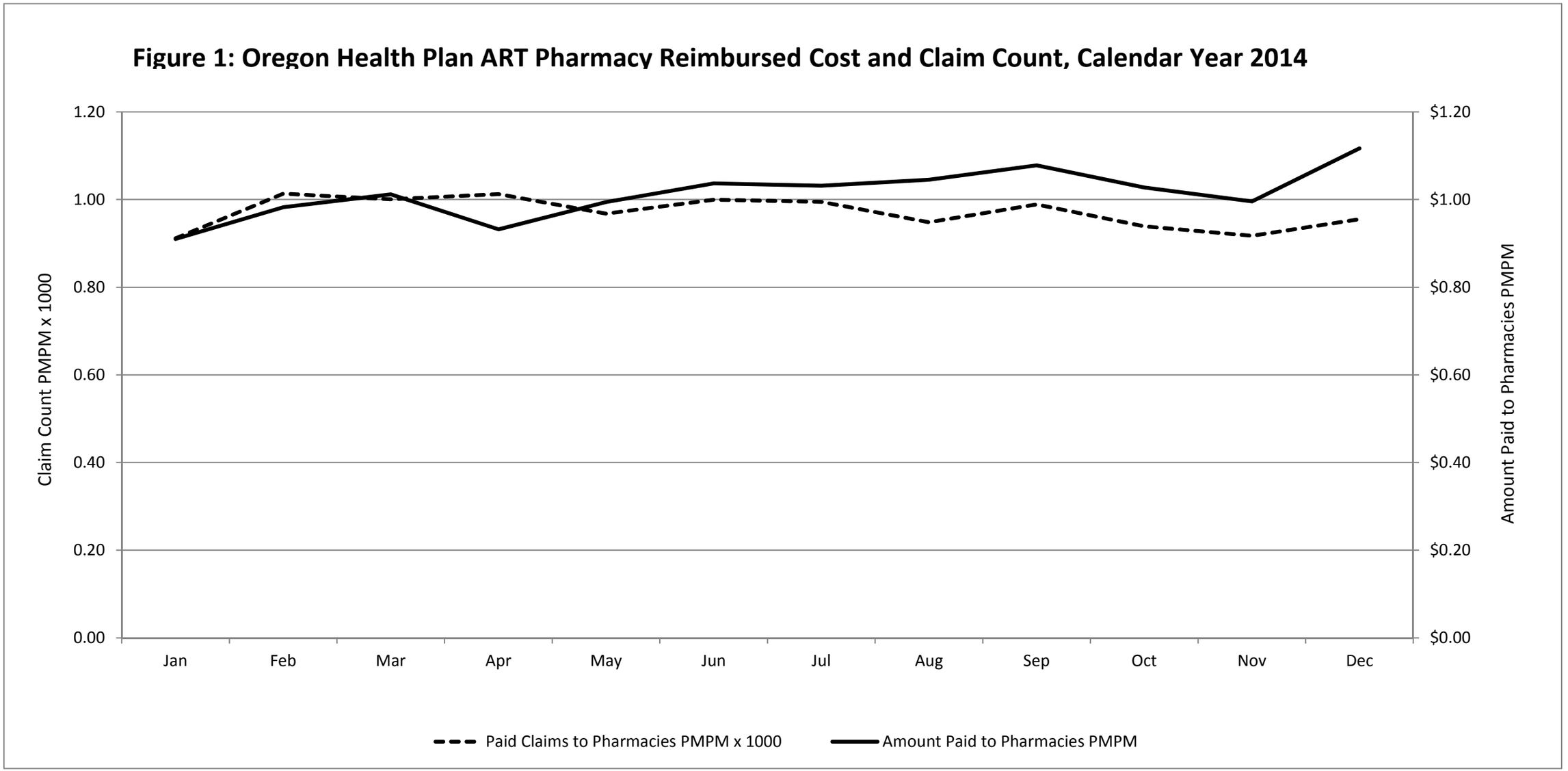
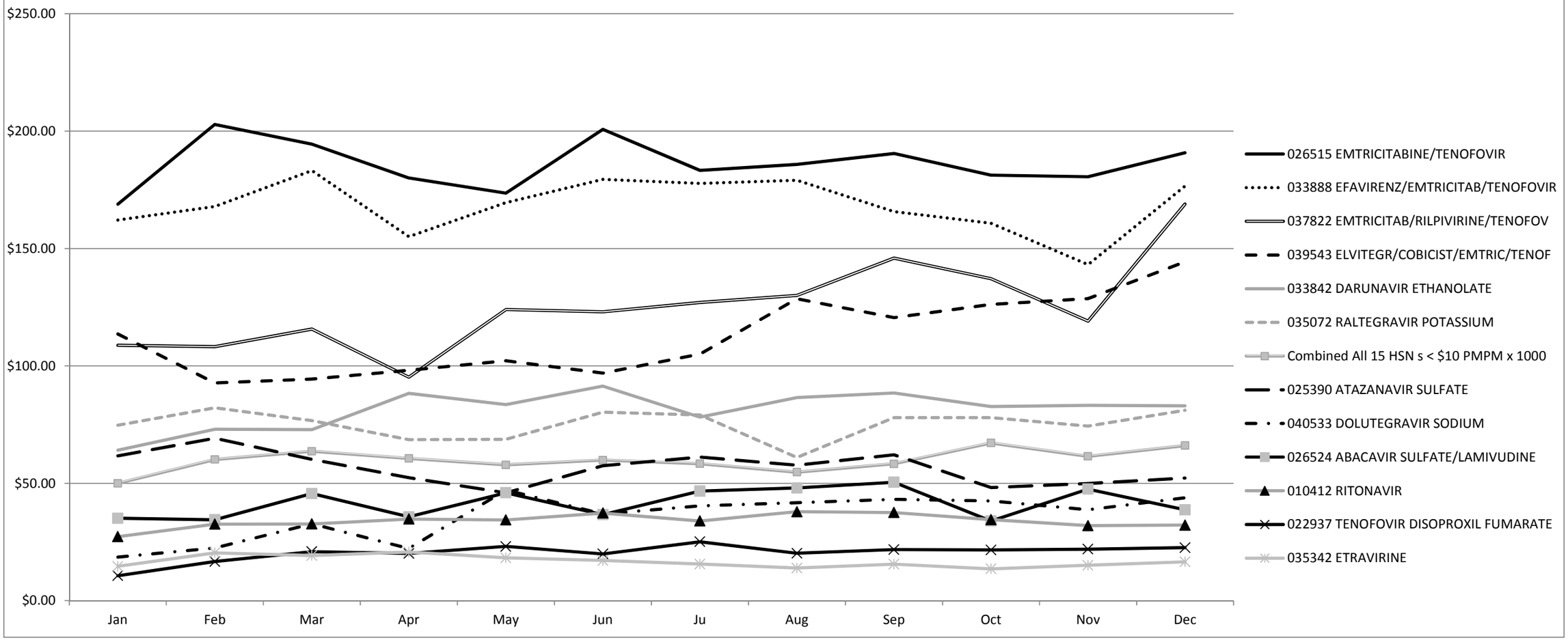


Figure 2 shows an increasing trend in the use of combination drugs, which are generally more expensive but result in fewer pharmacy claims. The combination of emtricitabine/tenofovir (Truvada™) ranks first by cost, averaging $186.05 PMPM x 1000; the combination of efavirenz/emtrictabine/tenofovir (Atripla™) ranks second at $168.35 PMPM x 1000; the combination of emtriactabine/rilpivirine/tenofovir (Complera™) ranks third at $125.24 PMPM x 1000; and the combination of elvitegravir/cobicistat/emtricitabine/tenofovir (Stribild™) ranked fourth at $112.60 PMPM x 1000. The cost of Complera™ and Stribild™ increased about 50% over the last 6 months of 2014; all other ARV drug costs remained grossly unchanged.

Figure 2: Unique ART Drug by Reimbursed Pharmacy Costs PMPM x 1000, Calendar Year 2014



There were 672 patients identified with a paid FFS drug claim for an ARV drug identified in Appendix 1. Eight patients were excluded as patients only receiving hepatitis B therapy, leaving 664 patients as the OHP HIV Population. After exclusions for less than 75% of eligible days in calendar year 2014 (n=78) and Medicare Part D (n=15), the final HIV Study Population for this drug use evaluation is 571 patients. Table 1 displays the demographic characteristics of the Study Population which is similar to the characteristics of the HIV Population. The Study Population were primarily male (n=486, 84.1%) and ethnically diverse, with 224 (39.2%) identified as non-white. Significantly, most (n=542, 94.9%) patients had an HIV diagnosis of record during the study period.

Table 1 - Demographics

	OHP HIV Population		**HIV Study Population**	
N=	664	%	571	%
Mean age in years (range)	41.4	(0-64)	41.5	(0-64)
< 19 years	10	1.5%	7	1.2%
19-64 years	654	98.5%	564	98.8%
> 64 years	0	0.0%	0	0.0%
Female	99	14.9%	85	14.9%
White	401	60.4%	347	60.8%
HIV ICD9 Code (042xx, V08, 079.53 or 795.71) on any claim from CY2013-Q12015	623	93.8%	542	94.9%

Table 2 displays a snap shot of the "last" (i.e. most current drug) therapy each patient received in 2014. The top 10 ARV regimens account for 75.9% of therapies. There were 66 patients (11.6%) who received unique regimens and another 71 patients (12.4%) who received regimens shared by less than 5 patients. Eight of the top 10 ARV regimens are identified as highly recommended therapy by HHS for treatment-naïve patients.[3] The most commonly identified regimens consisted of the NRTI/NNRTI branded combination products Atripla™ (n=107, 18.7%) and Complera™ (n=79, 13.8%). Truvada™ was included in 5 of the top 10 ARV regimens. The net cost of the most common regimens varied from a low of about $34/day to a high of about $90/day. PI based therapies are some of the most expensive and INSI based therapies are some of the least expensive. Comparative net prices will be disclosed in executive session.

Table 2 - Incidence of Final Drug Therapy

Patient counts by drug combinations.
Combinations defined as mix of drugs in each patient's final 60 days of therapy in CY2014

HHS[1] Evidence grade*	Drug 1	Drug 2	Drug 3	Study Population 571	%
BI (Alternative Initial)^	EMTRICITAB/TENOFOVIR/EFAVIRENZ			107	18.7%
BI (Alternative Initial)^	EMTRICITAB/TENOFOV/RILPIVIRINE			79	13.8%
AI (Recommended Initial)	EMTRICITABINE/TENOFOVIR	RITONAVIR	DARUNAVIR ETHANOLATE	56	9.8%
AI (Recommended Initial)	EMTRIC/TENOF/*ELVITEGR*/COBICIST			55	9.6%
BI (Alternative Initial)	EMTRICITABINE/TENOFOVIR	RITONAVIR	ATAZANAVIR SULFATE	46	8.1%
AI (Recommended Initial)	EMTRICITABINE/TENOFOVIR	*RALTEGRAVIR POTASSIUM*		41	7.2%
AI (Recommended Initial)	EMTRICITABINE/TENOFOVIR	*DOLUTEGRAVIR SODIUM*		20	3.5%
	EMTRICITABINE/TENOFOVIR	NEVIRAPINE		15	2.6%
AI (Recommended Initial)	ABACAVIR SULFATE/LAMIVUDINE	*DOLUTEGRAVIR SODIUM*		8	1.4%
CI (Optional Initial)	ABACAVIR SULFATE/LAMIVUDINE	*RALTEGRAVIR POTASSIUM*		7	1.2%
	Other Combinations - Patient counts per unique combination of >1 and <=5			71	12.4%
	Other Combination - Only 1 patient per unique combination			66	11.6%

Nucleoside Reverse Transcriptase Inhibitors (NRTI); Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI); Protease Inhibitor (PI), *Integrase Inhibitor (INSTI)*

***A** (strong support), **B** (moderate support), **C** (optional), **I** (data from RCTs)

^ Previously "Recommended"

Table 3 displays the number of patients meeting the definition of post-exposure and pre-exposure prophylaxis. There were 12 patients (2.1%) with single claims in 2014 for the HHS recommended post-exposure therapy and no other ARV therapy in the 90-days prior or after. Only 4 patients (0.7%) received only claims for Truvada™ in 2014 and none had an HIV diagnosis during the study period.

Table 3 - HIV Prophylaxis in Study Population

	Study Population	
N=	571	%
Post-exposure prophylaxis	12	2.1%
Pre-exposure prophylaxis	4	0.7%

Table 4 summarizes the patient medication possession rate (MPR) by drug component. There were 231 patients (40.5%) with less than 90% MPR and 4 patients (0.7%) with exactly 480 days of several drugs each during the year. There were no patients using therapies identified as therapies to avoid by the HHS.

Table 4 - Length of Therapy in 2014

	Study Population	
	571	%
Average total length of therapy any ARV drug (min-max)	306	(4-425)*
Patients with all drugs MPR >= 90%	340	59.5%
Patient with any drug MPR < 90%	231	40.5%
Patients $\geq$ 480 Days Supply for any drug	4	0.7%

* *Can exceed 365 because the day supply of the last claim filled in 2014 is added to the total*

Table 5 displays the number of patients that met the HHS Office of Inspector General Indicators of drug diversion. Only 3 patients met the criteria for excessive dose and these are likely errors in the data entry of "Days Supply" by the pharmacy. The service dates indicate lower doses were likely used by the patient. There were no patients accessing excessive numbers of pharmacies and prescribers.

Table 5 – Office of Inspector General - Indicators of Diversion

	Study Population	
	571	%
Count of patients with ARV claim exceeding 2x recommended dose *	3	0.5%
Patient with >= 6 unique pharmacies for ARV claims, 2014 **	0	0.0%
Patient with >= 6 unique prescribers for ARV pharmacy claims, 2014 ***	0	0.0%
Unique patients meeting any of the above:	3	0.5%

*Note: Possibly to be day supply entry errors

** Note: Ten patients had 4 pharmacies. All the rest had 3 or less.

*** Note: One patient had 5 prescribers. Three patients had 4 prescribers. All the rest had 3 prescribers or less.

Limitations: Net drug cost estimates are based upon the most recent rebate rates used for invoicing, not collected rebates, and is expected to be an optimistic representation of net price. Furthermore, Invoices are prepared using federal rebate rates reported after claim payment, they are subject to dispute by manufacturers and are frequently missing.

Reporting the last ARV for each patient was used to capture the most current utilization patterns while still maintaining a single patient as the unit of analysis. The methods used to define the last ARV may have included drugs that have been discontinued in the current therapy and may have contributed to the multiple unique therapies reported. These methods may also have contributed to the low adherence rates found. It is recognized that patients that have failed prior ARV may be using ARV that is specifically directed by their own unique resistance patterns. This DUE is not focused on assessing the individual appropriateness of an individual's ARV but merely documenting the most common ARV prescribed at a point in time.

It is possible patients could be using clinic samples or paying cash for ARV that would not be captured in this analysis. Limiting the Study Population to those with 75% eligibility during the study period is an attempt to draw conclusions from a sample where these practices would be less likely. Interpretation of the low adherence rate and low prophylaxis rates are most affected by alternate drug sources.

References:

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Appendix 1 – Unique Antiretroviral Drugs Marketed in United States (HIC3 = W5C, W5I, W5J, W5K, W5L, W5M, W5N, W5O, W5P, W5Q, W5T, W5U, W5X)

Class	Generic Name	Brand Name	ABBR	Forms / Dose Frequency	Generic?
Cellular Chemokine Receptor 5 Antagonist (CCR5)	MARAVIROC	SELZENTRY	MVC	Tablet / BID	N
Fusion Inhibitor (FI)	ENFUVIRTIDE	FUZEON	T20	Subcutaneous / BID	N
Integrase Inhibitor (INSTI)	*DOLUTEGRAVIR SODIUM*	TIVICAY	DTG	Tablet / BID	N
Integrase Inhibitor (INSTI)	*ELVITEGRAVIR*	VITEKTA	EVG	Tablet / QD	N
Integrase Inhibitor (INSTI)	*RALTEGRAVIR POTASSIUM*	ISENTRESS	RAL	Tablet; Chew; Packet / BID	N
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**ABACAVIR SULFATE**	ZIAGEN	ABC	Solution; Tablet* / QD - BID	*Y
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**DIDANOSINE**	VIDEX	ddI	Capsule*; Solution / QD - BID	*Y
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**EMTRICITABINE**	EMTRIVA	FTC	Capsule; Solution / QD	N
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**LAMIVUDINE**	EPIVIR	3TC	Solution; Tablet / QD – BID	Y
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**STAVUDINE**	ZERIT	d4T	Capsule; Solution / BID	Y
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**TENOFOVIR DISOPROXIL FUMARATE**	VIREAD	TDF	Tablet; Powder / QD	N
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**ZIDOVUDINE**	RETROVIR	ZDV	Capsule; Syrup; Tablet; Intravenous/ BID – TID	Y
2 NRTI COMBO	**EMTRICITABINE/ TENOFOVIR**	TRUVADA		Tablet / QD	N
2 NRTI COMBO	**LAMIVUDINE/ ZIDOVUDINE**	COMBIVIR		Tablet / QD	Y
2 NRTI COMBO	**ABACAVIR SULFATE/LAMIVUDINE**	EPZICOM		Tablet / QD	N
3 NRTI COMBO	**ABACAVIR/LAMIVUDINE/ ZIDOVUDINE**	TRIZIVIR		Tablet / QD	Y
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	DELAVIRDINE MESYLATE	RESCRIPTOR	DLV	Tablet / QD	N
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	EFAVIRENZ	SUSTIVA	EFV	Capsule; Tablet / QD	N
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	ETRAVIRINE	INTELENCE	ETR	Tablet / BID	N
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	NEVIRAPINE	VIRAMUNE	NVP	Suspension; Tablet; Tablet ER / QD - BID	Y
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	RILPIVIRINE HCL	EDURANT	RPV	Tablet / QD	N
2 NRTI- 1 NNRIT COMBO	**EMTRICITAB/ TENOFOVIR /**RILPIVIRINE	COMPLERA		Tablet / QD	N
2 NRTI- 1 NNRIT COMBO	**EMTRICITAB/ TENOFOVIR /**EFAVIRENZ	ATRIPLA		Tablet / QD	N
2 NRTI – *1 INSTI* COMBO	**ABACAVIR SULFATE/LAMIVUDINE** *DOLUTEGRAVIR SODIUM*	TRIUMEQ*		Tablet / QD	N
2 NRTI – *1 INSTI* – CYP P450 Inhibitor COMBO	**EMTRIC/ TENOF** /*ELVITEGR*/COBICIST/	STRIBILD		Tablet / QD	N
Protease Inhibitor (PI)	**SAQUINAVIR MESYLATE**	INVIRASE	SQV	Capsule; Tablet / BID	N
Protease Inhibitor (PI)	**NELFINAVIR MESYLATE**	VIRACEPT	NFV	Tablet	N
Protease Inhibitor (PI)	**INDINAVIR SULFATE**	CRIXIVAN	IDV	Capsules / BID - TID	N
Protease Inhibitor (PI)	**FOSAMPRENAVIR CALCIUM**	LEXIVA	FPV	Suspension; Tablet / QD	N
Protease Inhibitor (PI)	**ATAZANAVIR SULFATE**	REYATAZ	ATV	Capsule; Packet / QD	N
Protease Inhibitor (PI)	**TIPRANAVIR**	APTIVUS	TPV	Capsule; Solution / BID	N
Protease Inhibitor (PI)	**DARUNAVIR ETHANOLATE**	PREZISTA	DRV	Suspension; Tablet / QD	N
PI + CYP P450 Inhibitor COMBO	**ATAZANAVIR /** COBICISTAT	EVOTAZ		Tablet / QD	N
PI + CYP P450 Inhibitor COMBO	**DARUNAVIR /** COBICISTAT	PREZCOBIX		Tablet / QD	N
PI + CYP P450 Inhibitor COMBO	**LOPINAVIR/** RITONAVIR	KALETRA	LPV/r	Solution; Tablet / QD -BID	N
CYP P450 Inhibitor	RITONAVIR	NORVIR	RTV	Capsule; Solution; Tablet / BID	N
CYP P450 Inhibitor	COBICISTAT	TYBOST		Tablet / QD	N

*Not included in analysis. One patient identified after study completed.