

Human Immunodeficiency Virus (HIV): 24 month predicted versus actual utilisation analysis of Biktarvy and Juluca

Drug utilisation sub-committee (DUSC)

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Abstract

Purpose

To review the predicted versus actual utilisation of bictegravir+emtricitabine+tenofovir alafenamide (Biktarvy) and dolutegravir+rilpivirine (Juluca) in the first 24 months of R/PBS listing.

The report also presents the utilisation of Biktarvy and Juluca in the context of the utilisation of other Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (R/PBS) listed medicines used in the management of Human Immunodeficiency Virus (HIV) and Pre-Exposure Prophylaxis (PrEP).

This report should be read in conjunction with the NPS MedicineWise report on HIV antiretroviral medicines 2021.

Date of listing on the Pharmaceutical Benefits Scheme (PBS)

Biktarvy was first R/PBS-listed for this indication on 1 March 2019. Juluca was first R/PBS-listed for this indication on 1 December 2018.

There are a variety of listings of drugs that are used to treat HIV. The first combination HIV therapy drug was listed on the R/PBS in the late 1990s. A complete list of HIV medications available on the R/PBS can be found in Attachment A.

Data Source / methodology

The analysis used data from Services Australia supplied prescriptions database.

Key Findings

- The [REDACTED] of Biktarvy was substantially [REDACTED] than predicted. By year 2 of listing, the actual number of prescriptions dispensed was [REDACTED] percent [REDACTED] than predicted.

- The utilisation of Juluca was significantly less than predicted. By year 2 of listing, the actual number of prescriptions dispensed was ■ percent less than predicted.
- The listings of Biktarvy and Juluca were expected to realise savings to the R/PBS through substitution of existing listings. Since the listings of Biktarvy and Juluca, the overall expenditure on HIV R/PBS listings has fallen (Figure 5), however not as much as was predicted.

Over the period 2013-2021

- Since 2013 the use of all single drug HIV prescriptions has fallen. Dolutegravir was the anomaly over this period, with use increasing in prevalent patients until the last quarter (Q4) of 2018, when its use also started falling. Despite dolutegravir's prescription rate for initiating patients falling from 2014 levels, it was the highest single drug HIV medication prescribed until Q2 2019 when valganciclovir became slightly more popular.
- The picture with combination HIV drugs is less clear, however it is notable that since its listing in March 2019, Biktarvy has risen to be the leading combination medication prescribed for both initiating and prevalent patients. In 2020 Biktarvy was prescribed at just over double the rate of the next highest prescribed combination HIV medication, Dolutegravir + Abacavir + Lamivudine, which had been the leading combination HIV medication prescribed since 2017.
- The amount of patients initiating HIV medication has remained at a consistent level over time, while the number of prevalent patients showed a steady climb until Q1 2020 when the number of patients dropped, most likely because of the impact of the COVID-19 pandemic. By Q3 2020 the number of treated patients had almost returned to their pre-COVID level, however they were still slightly lower. The number of patients supplied a HIV listing has continued to fall slightly over Q4 2020 and Q1 2021.
- The number of patients initiating on PrEP has fallen slightly since the listing of tenofovir disoproxil + emtricitabine on the PBS. The number of prevalent patients on PrEP medication increased since listing, but fell between the first and second quarter of 2020, most likely due to the effect of social distancing in response to the COVID-19 pandemic in Australia. The number of prevalent patients supplied a PrEP listing has since returned to its pre-COVID level.

Purpose of analysis

To review the predicted versus actual utilisation of bictegravir with emtricitabine and tenofovir alafenamide (BIC/FTC/TAF)(Biktarvy®) and Dolutegravir + rilpivirine (DTG/RPV) (Juluca®). The report also presents the utilisation of Biktarvy and Juluca in the context of the utilisation of other R/PBS-listed medicines used in the management of Human Immunodeficiency Virus (HIV) and Pre-Exposure Prophylaxis (PrEP).

Biktarvy was first R/PBS-listed for this indication on 1 March 2019. Juluca was first R/PBS-listed for this indication on 1 December 2018.

The HIV / PrEP medicines considered in this analysis are:

Abacavir, Abacavir + Lamivudine, Abacavir + Lamivudine + Zidovudine, Aciclovir, Atazanavir, Atazanavir + Cobicistat, Bictegravir + Emtricitabine + Tenofovir Alafenamid, Darunavir, Darunavir + Cobicistat, Darunavir + Cobicistat + Emtricitabine + Tenofovir, Didanosine, Dolutegravir, Dolutegravir + Abacavir + Lamivudine, Dolutegravir + Lamivudine, Dolutegravir + Rilpivirine, Efavirenz, Emtricitabine, Emtricitabine + Rilpivirine + Tenofovir Alafenamid, Emtricitabine + Tenofovir Alafenamide, Enfuvirtide, Etravirine, Fanciclovir, Fosamprenavir, Ganciclovir, Indinavir, Lamivudine, Lamivudine + Zidovudine, Lopinavir + Ritonavir, Maraviroc, Nevirapine, Raltegravir, Rilpivirine, Ritonavir, Saquinavir, Stavudine, Tenofovir Alafenamide + Emtricitabine + Elvitegravir, Tenofovir Disoproxil, Tenofovir Disoproxil + Emtricitabine, Tenofovir Disoproxil + Emtricitabine + Efavirenz, Tenofovir Disoproxil + Emtricitabine + Elvitegravir, Tenofovir Disoproxil + Emtricitabine + Rilpivirine, Tipranavir, Valganciclovir, Zidovudine.

Background

Clinical situation

The HIV virus attacks the body's immune system. Left untreated it will cause severe damage to the immune system within 10 years and the development of acquired immunodeficiency syndrome (AIDS). HIV is transmitted through unprotected sex, by blood-to-blood contact including through injecting drug use, and from mother to child. Currently HIV cannot be cured but can be controlled with effective treatments that enable people living with HIV (PLWHIV) to live long healthy lives and to protect their partners from infection.³

It has been estimated that 0.14% of the Australian population, or approximately 27,500 Australians, are living with HIV.⁴ Since 2012, there has been a general trend towards fewer new HIV diagnoses being made each year. This is thought to be due to more people living with HIV being aware of their HIV status, earlier treatment of the disease and the strong uptake of PrEP among gay and bisexual men. However, in 2019, the number of Australian diagnosed with HIV increased from 839 in 2018 to 901 in 2019.⁵

Most new infections are in males. The number of cases that have been transmitted through male to male sex has fallen substantially in the last 5 years while transmission via

heterosexual sex or due to overseas infections have remained steady. While numbers are small, the rate at which Aboriginal and Torres Strait Islander people are diagnosed with HIV is higher than for other Australians. In 2017, the notification rate among Aboriginal and Torres Strait Islander people was 1.6 times higher than in other Australians.^{4,5}

In 2018, PrEP was added to the PBS. PrEP involves HIV negative people taking antiretroviral drugs to protect them and prevent HIV infection.

Treatment

HIV is not curable. However, antiretroviral medicines significantly reduce HIV-related morbidity, mortality and transmission of the virus to others. As a result, HIV infection is now seen as a manageable chronic condition.

Since 2015, Australian guidelines have recommended antiretroviral medicines as soon as possible for all patients diagnosed with HIV infection irrespective of clinical stage, HIV viral load¹ and CD4+ count.⁶

There are six classes of antiretroviral medicines available in Australia. Each target HIV at different stages of the life cycle and different medicines from different classes are used in combination to suppress the virus. At least three antiretroviral drugs are needed for initial therapy although some patients can change to a two-drug regimen once viral suppression is achieved.⁷

The different classes of medicines include the⁸⁻¹⁰:

- nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs); abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir and zidovudine
- non-nucleoside reverse transcriptase inhibitors (NNRTIs); efavirenz, etravirine, nevirapine and rilpivirine
- HIV protease inhibitors (HIV-PIs); atazanavir, darunavir, fosamprenavir, lopinavir, ritonavir, saquinavir and tipranavir
- integrase strand transfer inhibitors (INSTIs); bictegravir, dolutegravir, elvitegravir and raltegravir
- entry inhibitors
 - fusion inhibitors; enfuvirtide
 - CCR5 inhibitors; maraviroc.

Guidelines recommend taking into account both patient and regimen-specific factors, such as efficacy, potential adverse effects, potential drug-drug interactions, comorbidities and coinfections, pregnancy status, ease of use and preferences when choosing initial treatment regimens. However, the following initial treatment regimens are recommended for most PLWHIV:⁸

- bictegravir plus tenofovir alafenamide plus emtricitabine

¹ Viral load refers to the number of HIV particles per unit of blood. A high viral load is an indication of untreated or poorly controlled HIV infection

- dolutegravir plus abacavir plus lamivudine²
- dolutegravir plus (emtricitabine or lamivudine) plus (tenofovir alafenamide or tenofovir disoproxil fumarate)
- dolutegravir plus lamivudine³
- raltegravir plus (emtricitabine or lamivudine) plus (tenofovir alafenamide or tenofovir disoproxil).

Table 1 shows the various combinations of medicines that can be used for each of the above regimens.

Table 1: Options for recommended initial antiretroviral regimens

Regimen	Combinations of medicines
bictegravir plus tenofovir alafenamide plus emtricitabine	bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)
dolutegravir plus abacavir plus lamivudine	abacavir + dolutegravir + lamivudine (Triumeq) OR abacavir + lamivudine (Kivexa) plus dolutegravir (Tivicay) OR dolutegravir + lamivudine (Dovato) plus abacavir (Ziagen) OR dolutegravir (Tivicay) plus abacavir (Ziagen) plus lamivudine (various brands)
dolutegravir plus (emtricitabine or lamivudine) plus (tenofovir alafenamide or tenofovir disoproxil fumarate)	dolutegravir + lamivudine (Dovato) plus tenofovir disoproxil (various brands) OR dolutegravir (Tivicay) plus emtricitabine + tenofovir alafenamide (Descovy) OR dolutegravir (Tivicay) plus emtricitabine + tenofovir disoproxil (Truvada and generics)
dolutegravir plus lamivudine	dolutegravir + lamivudine (Dovato) OR dolutegravir (Tivicay) plus lamivudine (various brands)
raltegravir plus (emtricitabine or lamivudine) plus (tenofovir alafenamide or tenofovir disoproxil)	raltegravir (Isentress) plus emtricitabine + tenofovir alafenamide (Descovy) OR raltegravir (Isentress) plus emtricitabine + tenofovir disoproxil (Truvada and generics) OR raltegravir (Isentress) plus lamivudine (various brands) plus tenofovir disoproxil (various brands)

² Only for individuals who are HLA-B*5701 negative and without chronic hepatitis B virus (HBV) coinfection

³ Not recommended for individuals with HIV RNA >500,000 copies/mL, HBV co-infection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available

The other antiretrovirals are largely reserved for treatment of drug-resistant strains of HIV.⁶

Prescribing ART in patients with comorbidities

Given antiretroviral medicines are used indefinitely, and patients with HIV now live for many years with the condition, there is a need to consider the adverse effects of these medicines on comorbidities or the risk of developing conditions such as cardiovascular or kidney disease. A number of antiretroviral medicines have adverse effect profiles that mean they should be avoided or used cautiously in patients with certain comorbidities or risk factors, including:^{8,10}

- cardiovascular disease (CVD) or high risk of CVD (diabetes, hypertension, hyperlipidaemia);
- mental health conditions (e.g., depression);
- chronic kidney disease (CKD) or risk of CKD (diabetes, hypertension); and
- osteoporosis.

Pharmacology

The different classes of antiretroviral medicines target HIV at different stages of the life cycle:⁹

- the NRTIs inhibit viral reverse transcriptase and viral DNA synthesis, preventing HIV replication;
- the NNRTIs reversibly inhibit HIV-1 reverse transcriptase, reducing viral DNA synthesis;
- the HIV-PIs inhibit HIV-1 and HIV-2 proteases, preventing viral maturation and replication;
- the INSTIs inhibit HIV integrase, which prevents viral replication by stopping insertion of viral DNA into the host DNA;
- enfuvirtide binds to viral glycoprotein subunit gp41 and, by inhibiting its function, blocks viral fusion with the CD4 receptor of the host cell and thus viral entry to the cell;
- maraviroc prevents the entry of CCR5-tropic (R5) strains of HIV by selectively binding to the CCR5 receptor.

Therapeutic Goods Administration (TGA) approved indications

A summary of the TGA approved indication for each of the antiretroviral HIV medicines can be found in Appendix A.

Most are registered for the treatment (alone or in combination) for the treatment of HIV-1 infection in adults and children. Maraviroc is only indicated for adult patients infected with CCR5-tropic HIV-1.

Emtricitabine + tenofovir alafenamide (Descovy) and tenofovir disoproxil + emtricitabine (Truvada) are also indicated for PrEP.

Lamivudine as a single active ingredient is also indicated for chronic hepatitis B with evidence of hepatitis B virus (HBV) replication.

Dosage and administration

The dose and frequency of administration of antiviral HIV medicines listed on the PBS is summarised in Appendix B.⁹

The current Product Information (PI) and Consumer Medicine Information (CMI) documents are available through [the TGA website product information access page](#) and [the TGA website consumer medicines information access page](#).

PBS listing details (as at July 2021)

Table 2 lists the antiretroviral medicines for the treatment of HIV by medicine class. It also includes a summary of the listing dates and relevant changes to the listings of HIV medicines from 2013 onwards.

Current PBS listing details are available from www.pbs.gov.au

Table 2: Antiretroviral medicines listed for the treatment of HIV, by drug class, as at July 2021

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
Nucleoside analogue reverse transcriptase inhibitors	abacavir (Ziagen)	J05AF06	10294T (listed July 2015) 10356C (listed July 2015)
	lamivudine + zidovudine (Combivir)	J05AR01	10284G (listed July 2015)
	didanosine (Videx EC)	J05AF02	10313T (listed July 2015; deleted May 2018) 10364L (listed July 2015; deleted May 2018)
	emtricitabine (Emtriva)	J05AF09	10274R (listed July 2015, deleted Sep 2018)
	abacavir + lamivudine (Kivexa)	J05AR02	10357D (listed July 2015) 11246X (listed Feb 2018)
	lamivudine (Zeffix and various generics)	J05AF05	10311Q (listed July 2015) 10320E (listed July 2015) 10348P (listed July 2015)
	stavudine (Zerit)	J05AF04	10271N (listed July 2015; deleted May 2018) 10312R (listed July 2015; deleted May 2018)
	abacavir + lamivudine + zidovudine (Trizivir)	J05AR04	10305J (listed July 2015)
	emtricitabine + tenofovir disoproxil (Truvada, Apotex, Cipla)	J05AR03	10347N (listed July 2015; deleted July 2017) 10946D (listed Dec 2016; deleted Apr 2017)

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
			10966E (listed Dec 2016; deleted Apr 2017) 11146P (listed June 2021) 11149T (listed June 2021) 12506F (listed June 2021)
	emtricitabine + tenofovir alafenamide (Descovy)	J05AR17	11099E (listed May 2017) 11113X (listed May 2017)
	tenofovir disoproxil (Viread)	J05AF07	10310P (listed July 2015; deleted July 2017) 11142K (listed Aug 2017) 11155D (listed Aug 2017)
	zidovudine (Retrovir)	J05AF01	10266H (listed July 2015) 10360G (listed July 2015) 10361H (listed July 2015)
Non-nucleoside analogue reverse transcriptase inhibitors	efavirenz (Stocrin)	J05AG03	10275T (listed July 2015) 10336B (listed July 2015) 10366N (listed July 2015)
	etravirine (Intelence)	J05AG04	10301E (listed July 2015)
	nevirapine (Viramune)	J05AG01	10303G (listed July 2015) 10304H (listed July 2015) 10319D (listed July 2015)
	rilpivirine (Edurant)	J05AG05	10298B (listed July 2015)
Protease inhibitors	atazanavir (Reyataz)	J05AE08	10276W (listed July 2015; deleted Mar 2020) 10321F (listed July 2015) 10349Q (listed July 2015) 11657M (listed April 2019)
	darunavir (Prezista)	J05AE10	10367P (listed July 2015)
	darunavir + cobicistat (Prezcobix)	J05AR14	10903W (listed Oct 2016)
	fosamprenavir (Telzir)	J05AE07	10337C (listed July 2015)
	indinavir (Crixivan)	J05AE02	10363K (listed July 2015; deleted Sep 2018)
	lopinavir+ ritonavir (Kaletra)	J05AR10	10272P (listed July 2015) 10285H (listed July 2015) 10327M (listed July 2015)
	ritonavir (Norvir)	J05AE03	10273Q (listed July 2015) 10300D (listed July 2015; deleted June 2019))
	saquinavir (Invirase)	J05AE01	10335Y (listed July 2015)
	tipranavir (Aptivus)	J05AE09	10344K (listed July 2015)
	atazanavir + cobicistat (Evotaz)	J05AR15	10692R (listed Apr 2016)

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
Entry inhibitors	enfuvirtide (Fuzeon)	J05AX07	10365M (listed July 2015)
	maraviroc (Celsentri)	J05AX09	10318C (listed July 2015) 10355B (listed July 2015)
Integrase inhibitors	dolutegravir (Tivicay)	J05AX12 J05AJ03	10283F (listed July 2015)
	raltegravir (Isentress)	J05AX08 J05AJ01	10286J (listed July 2015) 10299C (listed July 2015) 10326L (listed July 2015) 11248B (listed Feb 2018)
Combination class agents	efavirenz + emtricitabine + tenofovir disoproxil (Atripla)	J05AR06	10297Y (listed July 2015) 11732L (listed Aug 2019)
	rilpivirine + emtricitabine + tenofovir disoproxil (Eviplera)	J05AR08	10314W (listed July 2015; deleted Feb 2020)
	elvitegravir + cobicistat + tenofovir disoproxil + emtricitabine (Stribild)	J05AR09	10307L (listed July 2015; deleted Feb 2020)
	abacavir + dolutegravir + lamivudine (Triumeq)	J05AR13	10345L (listed July 2015)
	emtricitabine + rilpivirine + tenofovir alafenamide (Odefsey)	J05AR19	11104K (listed May 2017)
	elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	J05AR18	11114Y (listed May 2017)
	bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)	J05AR20	11649D (listed Mar 2019)
	dolutegravir + rilpivirine (Juluca)	J05AR21	11540J (listed Dec 2018)
	darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza)	J05AR22	11955F (listed Oct 2016)
dolutegravir + lamivudine (Dovato)	J05AR25	11843H (listed Dec 2019; deleted Nov 2020)	

Restriction

Current R/PBS listing details and restriction details are available from the [PBS website](#).

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

Details on the PBAC's considerations of listing dolutegravir and rilpivirine (DTG/RPV)(Juluca) on the PBS can be found in the [July 2018 Public Summary Document for Juluca](#).

Details on the PBAC's considerations of listing bictegravir with emtricitabine and tenofovir alafenamide (BIC/FTC/TAF)(Biktarvy) on the PBS can be found in the [March 2018 Public Summary Document for Biktarvy](#).

Previous reviews by the DUSC

DUSC reviewed the predicted vs. actual utilisation for the HIV drugs atazanavir, enfuvirtide, fosamprenavir (listed 1 October 2004) and emtricitabine (listed 1 April 2005) at its February 2007 meeting. DUSC noted that the total expenditure on HIV pharmacotherapies continued to increase. DUSC considered that it was unclear whether a greater number of patients were being treated for HIV or whether patients were being treated for longer periods.

DUSC further reviewed the utilisation of HIV medicines in February 2013. The main findings from that review were:

- In 2011/12 the PBS & RPBS (R/PBS) expenditure on medicines supplied for the treatment of HIV was \$201.1 million. This was an 8% increase compared to the previous financial year.
- The PBS HIV medicines prescriptions data had a limitation that prevented patient level analysis (e.g. determining patient treatment pathways, co-administration of products or comparison of treatment naïve and experienced patients). This limitation was due to the majority of prescriptions being prescribed in public hospitals and the majority of these being processed via a bulk processing system that did not record a patient identifier.

DUSC considered that the increasing utilisation of medicines for the treatment of HIV infection aligned with the increasing population of people living with HIV, increased awareness and diagnosis, lifelong therapy, and government endorsed treatment targets. From the available data, DUSC considered that prescribing was in accordance with clinical guidelines. DUSC noted that a number of fixed dose combination products were available, and as combination therapy is indicated for first and subsequent lines of therapy, considered these products to be an important aspect of the management of HIV infection. DUSC also noted a shift in best practice recommendations towards earlier initiation of treatment. In 2013, the PBS restrictions for most products limited their use to patients with a CD4 count less than 500 per cubic millimetre or symptomatic HIV.

Methods

PBS and RPBS (R/PBS) prescription data for PBS-listed HIV treatment and PrEP items were extracted from the Services Australia prescription database for the period July 2013 to June 2021 inclusive, based on the date that the prescription was supplied. Data for this period includes all R/PBS supplies regardless of whether a subsidy was paid; i.e. both over co-payment and under co-payment. HIV treatment and PrEP items were defined as those that had the text "HIV" in the PBS restriction and were in the ATC group J05A (Antivirals for systemic use).

The medicine foscarnet fulfilled these criteria, however all its items and restrictions were not for the treatment of HIV, but for the treatment of other conditions for patients with HIV. Thus foscarnet was excluded from the extract. A complete list of medicines and items included in the analyses can be found in Appendix C.

A group of tenofovir disoproxil items (6358P, 9563H, 10310P, 11142K, 11155D) are listed for both HIV treatment and chronic hepatitis B infection. To assign the correct indication for individual prescriptions of these item numbers, the prescription was linked to the Services Australia authority approvals database to determine the assigned authority restriction number and hence the indication. Likewise, the famciclovir item 8896F is listed for both HIV and herpes treatment. Again the indication was determined by linking to the authority approvals database. PrEP items are the following tenofovir disoproxil + emtricitabine items 11276L, 11296M, 11306C and 12542D.

The data were extracted for date of supply from 1 July 2013, as this was the date from which the patient level prescription data was complete for Highly Specialised Drug (HSD) data (all the extracted items are from the HSD section of the PBS schedule). Prior to this, part of the HSD supply was processed through a Services Australia bulk processing system and was not included in the patient level prescription data.

The R/PBS prescription data were used to determine the number of prescriptions supplied, R/PBS expenditure. These prescription data were also used to count the number of patients, both incident (new to pharmacological treatment) and prevalent (number treated) in each time period. The number of prevalent patients was determined by counting the number of people supplied at least one PBS prescription using person-specific numbers (non-identifying) in the data for the specified time periods. Patient initiation date was defined as the date of supply of the first PBS or RPBS prescription of a medicine (since 1 July 2013). As some of the medicines were listed prior to 1 July 2013, initiating patient counts are only reported from 1 July 2014. This means that initiating patients have no script since 1 July 2013 and at least 12 months with no prior prescription.

As these analyses use date of supply prescription data, there may be small differences compared with publicly available Services Australia Medicare date of processing data. These data only include subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included.

Results

Analysis of drug utilisation

Overall utilisation

The number of R/PBS prescriptions for combination HIV medications supplied since July 2013 is shown in Figure 1a and 1b.

The number of R/PBS prescriptions for single HIV medications supplied since July 2013 is shown in Figure 2a and 2b.

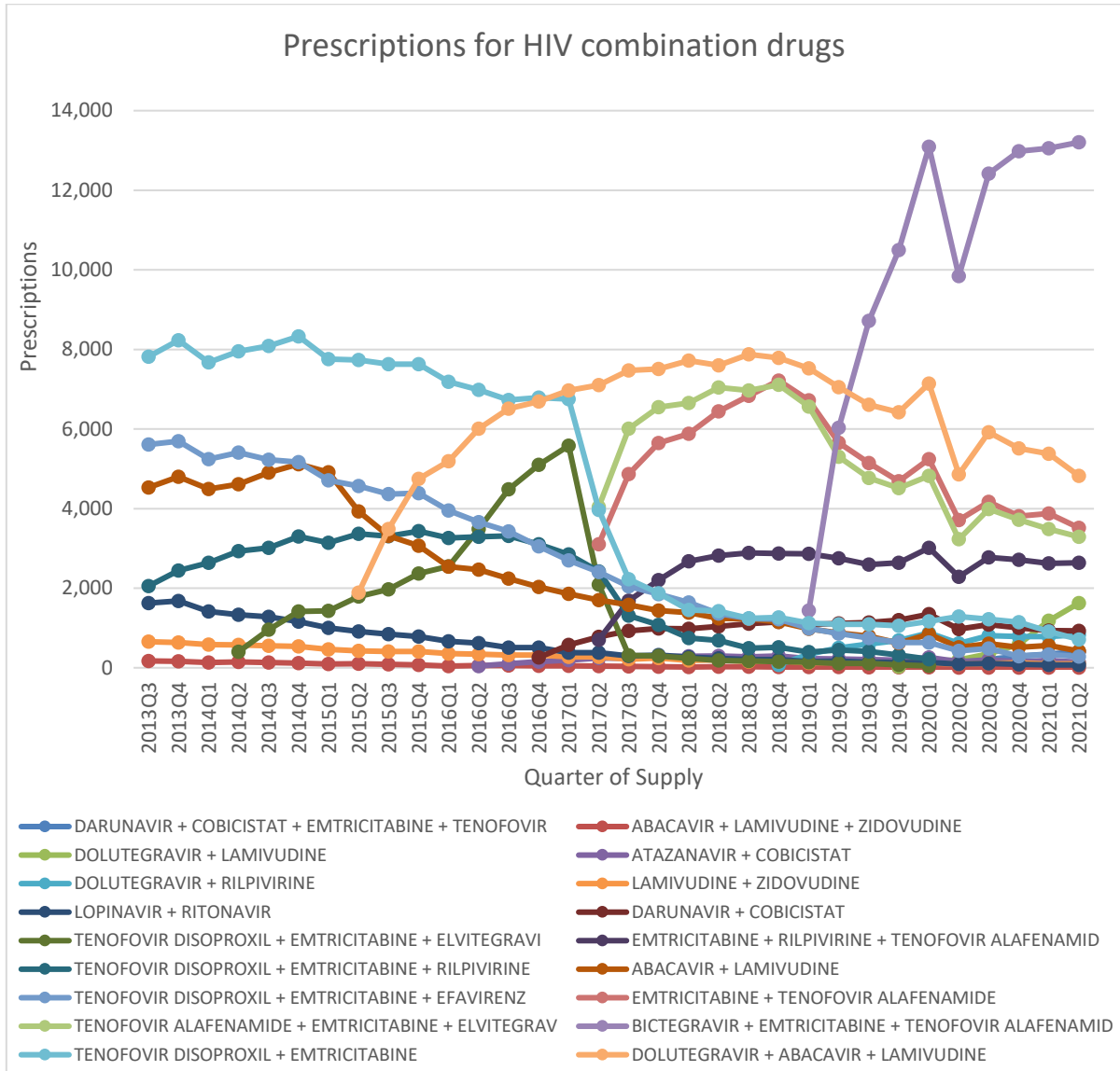


Figure 1a: Number of PBS/RPBS combination drug HIV prescriptions supplied per quarter by regimen

Source: Services Australia prescriptions database, extracted August 2021

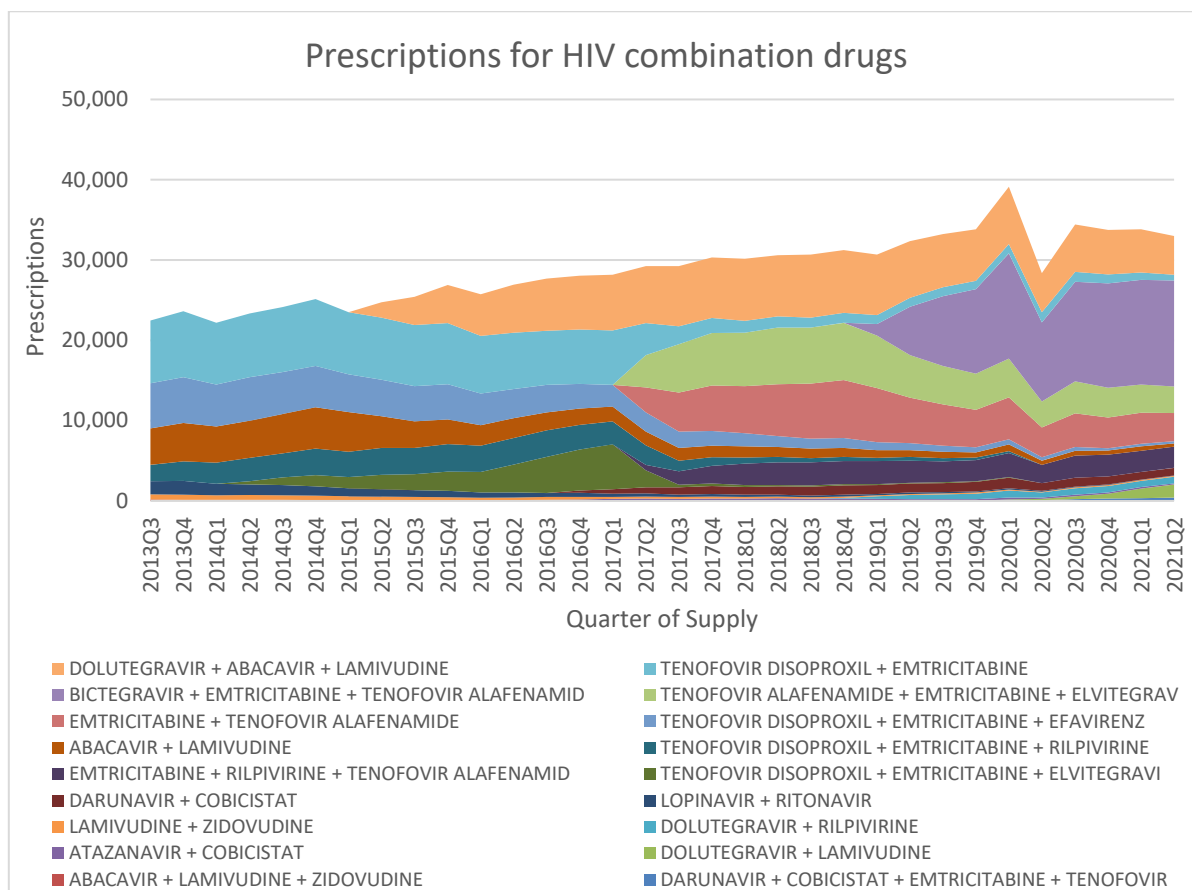


Figure 1b: Total number of PBS/RPBS combination drug HIV prescriptions supplied per quarter

Source: Services Australia prescriptions database, extracted August 2021.

Figures 1a and 1b show an increase in the overall use of combination HIV medicines over time until 2020 where the growth in dispensed prescriptions had slowed. The highest combined prescription HIV medicine in 2020 and 2021 was Biktarvy, which was prescribed more than 2.5 times the second most prescribed combination HIV medication dolutegravir abacavir lamivudine.

The effect of COVID-19 on the script numbers is evident in the spike increase in the last quarter of 2019, followed by a sharp decrease in the first quarter of 2020, with numbers stabilising from the second quarter of 2020.

The number of R/PBS prescriptions for single HIV medications supplied since July 2013 is shown in Figure 2a and 2b.

Since 2013 the use of all single drug HIV prescriptions has fallen. Dolutegravir was the anomaly over this period, with use increasing in prevalent patients until the last quarter of 2018, when its use also started falling. Despite dolutegravir's prescription rate for initiating patients falling from 2014 levels, it has been the highest single drug HIV medication prescribed since the last quarter of 2016.

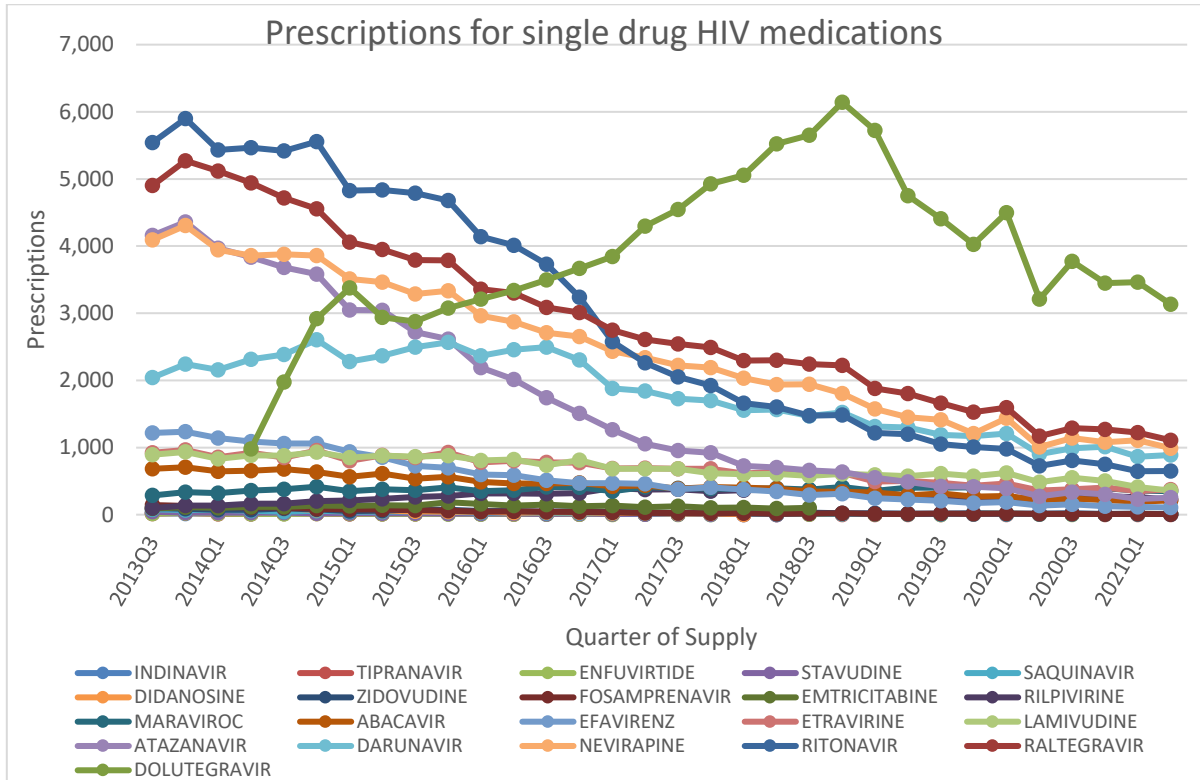


Figure 2a: Number of PBS/RPBS single drug HIV prescriptions supplied per quarter
 Source: Services Australia prescriptions database, extracted August 2021

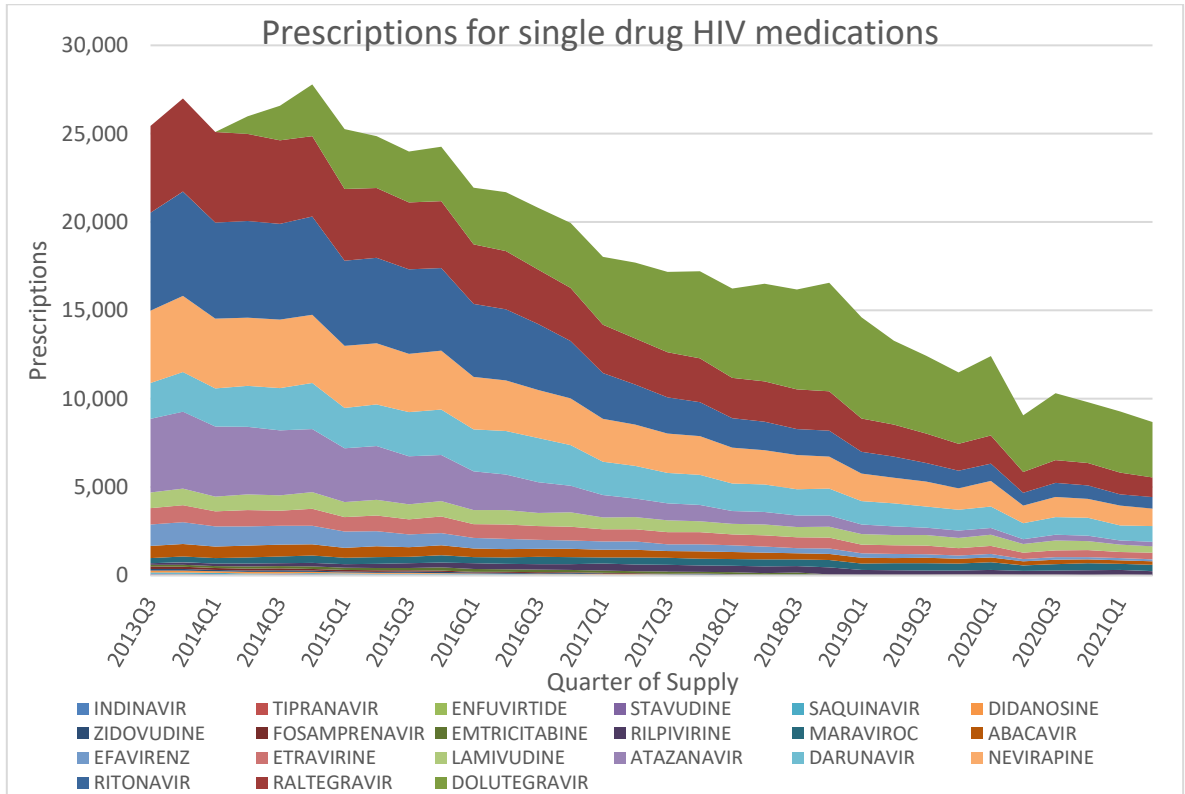


Figure 2b: Total number of PBS/RPBS single drug HIV prescriptions supplied per quarter
 Source: Services Australia prescriptions database, extracted August 2021

Dolutegravir has been the highest single prescribed medication for HIV in 2020 and 2021, it has been prescribed almost three times more than the next most prescribed single HIV medication, raltegravir.

The overall trend in all single prescription HIV medication (if dolutegravir is removed) is an initial high prescription rate, followed by a tapered drop off, with this being more dramatic in the higher frequency prescription medications. Dolutegravir took a few quarters to begin take-up with prescriptions accelerating until the final quarter of 2018, at which point prescriptions began to fall.

Table 3 shows the total prescription count for HIV drug prescriptions since 2013. Looking at the yearly totals, the prescription count of HIV medications has been dropping since 2014 from 206,136 to 180,531 in 2020. This might be due to the increase in prescribing combination HIV drugs and the fall in prescribing single drug therapies.

A predicted versus actual utilisation analysis of the highlighted medications, Biktary and Juluca, has been undertaken as part of this report.

Table 3: HIV drug prescription count by year.

Drug Name / Prescription Count	2013	2014	2015	2016	2017	2018	2019	2020	2021	Grand Total
DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE			10,124	24,407	29,061	30,988	27,613	23,429	10,202	155,824
TENOFOVIR DISOPROXIL + EMTRICITABINE	16,050	32,040	307,49	27,683	14,815	5,382	4,363	4,821	1,627	137,530
DOLUTEGRAVIR		5,873	12,269	13,709	17,611	22,370	18,905	14,927	6,600	112,264
BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMID							26,682	48,338	26,262	101,282
RALTEGRAVIR	10,172	19,333	15,583	12,754	10,392	9,055	6,870	5,320	2,332	91,811
RITONAVIR	11,441	21,871	19,122	15,124	8,814	6,221	4,476	3,268	1,299	91,636
TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAV					16,601	27,772	21,149	15,759	6,776	88,057
EMTRICITABINE + TENOFOVIR ALAFENAMIDE					13,619	26,384	22,210	16,934	7,396	86,543
TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ	11,304	21,048	18,031	14,090	9,008	5,454	3,236	1,825	614	84,610
NEVIRAPINE	8,395	15,536	13,593	11,198	9,187	7,718	5,644	4,666	2,097	78,034
ABACAVIR + LAMIVUDINE	9,325	19,132	15,229	9,273	6,579	5,004	3,270	2,480	978	71,270
DARUNAVIR	4,284	9,461	9,711	9,624	7,149	6,109	4,969	4,117	1,752	57,176
TENOFOVIR DISOPROXIL + EMTRICITABINE + RILPIVIRINE	4,492	11,876	13,242	12,965	7,648	2,441	1,568	217		54,449
ATAZANAVIR	8,515	15,069	11,425	7,450	4,196	2,729	1,879	1,302	488	53,053

Drug Name / Prescription Count	2013	2014	2015	2016	2017	2018	2019	2020	2021	Grand Total
EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMID					4,594	11,261	10,848	10,784	5,263	42,750
TENOFOVIR DISOPROXIL + EMTRICITABINE + ELVITEGRAVI		2,775	7,567	15,624	8,277	744	431	48		35,466
TENOFOVIR DISOPROXIL	2,372	4,196	3,696	3,574	3,325	3,452	2,711	2,093	803	26,222
LAMIVUDINE	1,825	3,526	3,469	3,182	2,662	2,391	2,355	2,159	769	22,338
ETRAVIRINE	1,886	3,585	3,463	3,137	2,750	2,491	1,901	1,607	727	21,547
DARUNAVIR + COBICISTAT				257	3,269	4,282	4,534	4,405	1,860	18,607
LOPINAVER + RITONAVER	3,304	5,185	3,545	2,295	1,374	922	594	430	145	17,794
EFAVIRENZ	2,452	4,347	3,217	2,164	1,714	1,321	850	605	225	16,895
ABACAVER	1,389	2,614	2,277	1,888	1,654	1,469	1,201	956	406	13,854
MARAVIROC	621	1,474	1,502	1,528	1,548	1,560	1,566	1,520	713	12,032
LAMIVUDINE + ZIDOVUDINE	1,289	2,247	1,709	1,339	1,011	713	531	451	198	9,488
RILPIVIRINE	231	666	984	1,265	1,496	1,507	993	985	488	8,615
DOLUTEGRAVER + RILPIVIRINE						72	2,125	3,085	1,613	6,895
ATAZANAVER + COBICISTAT				302	954	1,154	849	774	325	4,358
DOLUTEGRAVER + LAMIVUDINE							30	1,297	2,812	4,139
EMTRICITABINE	200	476	596	573	475	298				2,618
ABACAVER + LAMIVUDINE + ZIDOVUDINE	333	529	356	198	156	89	55	24	11	1,751
FOSAMPRENAVER	275	420	286	180	106	67	51	44	17	1,446
ZIDOVUDINE	188	314	260	204	135	106	74	65	20	1,366

Drug Name / Prescription Count	2013	2014	2015	2016	2017	2018	2019	2020	2021	Grand Total
DARUNAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR								586	753	1,339
DIDANOSINE	208	344	216	147	88	≤5				1,001 – 1,011
SAQUINAVIR	149	234	178	114	83	48	29	18	8	861
STAVUDINE	75	111	78	56	27	≤5				348 - 355
ENFUVRTIDE	43	52	43	21	10	30	31	30	21	281
TIPRANAVIR	40	58	50	35	31	14	12	13	6	259
INDINAVIR	39	81	59	39	19	≤5				235 - 245
Grand Total	100,897	204,473	202,628	196,395	190,438	191,628	184,605	179,382	85,606	1,536,057

Source: Services Australia prescriptions database, extracted August 2021

Note: Data begins in Q3 2013 and ends is Q2 2021.

Note: * indicates antiviral medications that

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Figure 3a shows initiating patients starting HIV combination therapy per quarter, while Figure 3b shows initiating patients starting single drug HIV therapy per quarter.

Figure 3a shows that the highest use of a combination HIV medication is when the medication is first listed on the PBS. After the initial high rates, there is a sharp decline, with usage tapering off over time.

Figure 3b shows that patients have mainly initiated treatment on dolutegravir, however this has been declining alongside the overall decline of single drug HIV therapy.

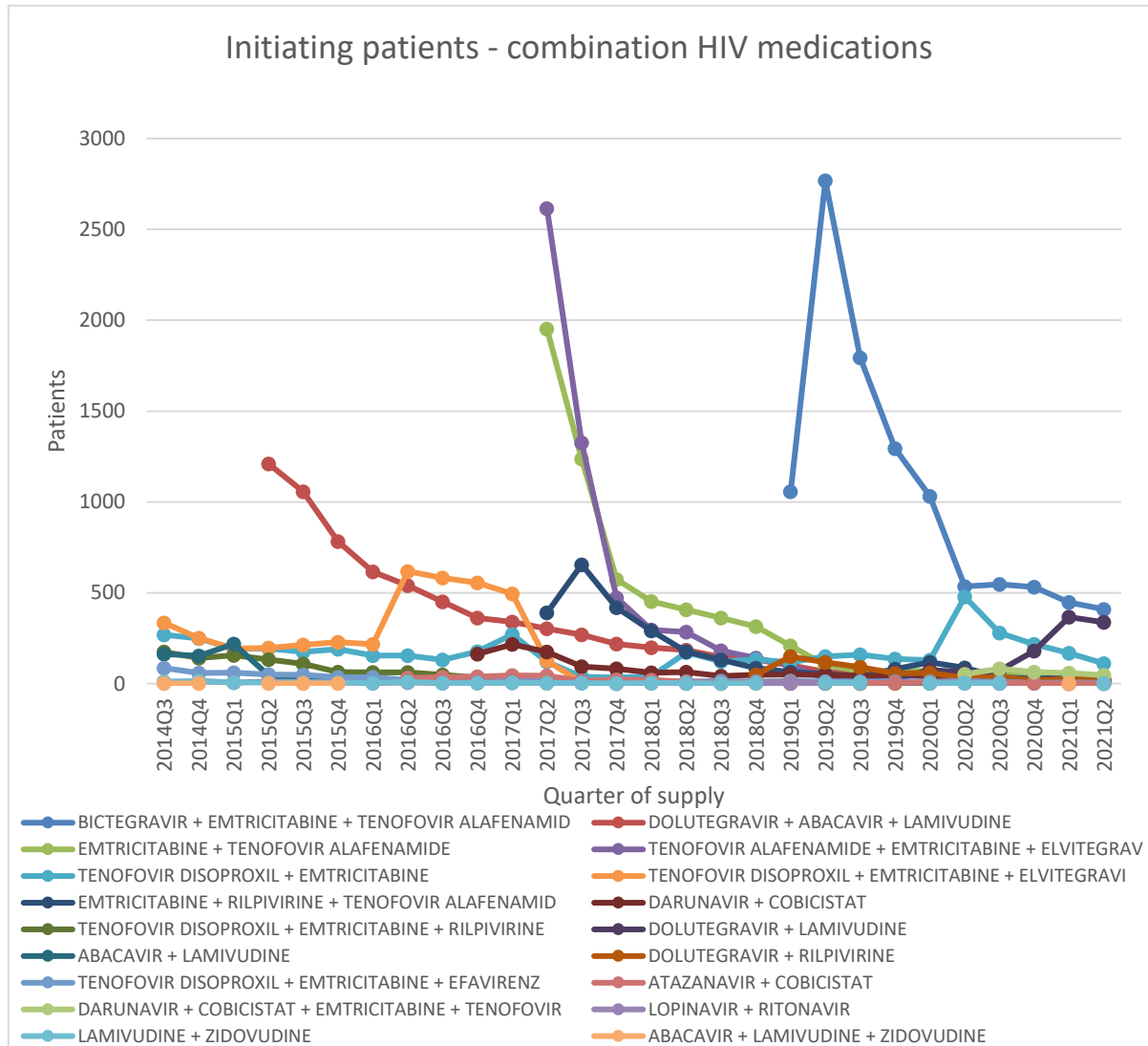


Figure 3a: Initiating patients receiving combination HIV medication per quarter

Source: Services Australia prescriptions database, extracted August 2021

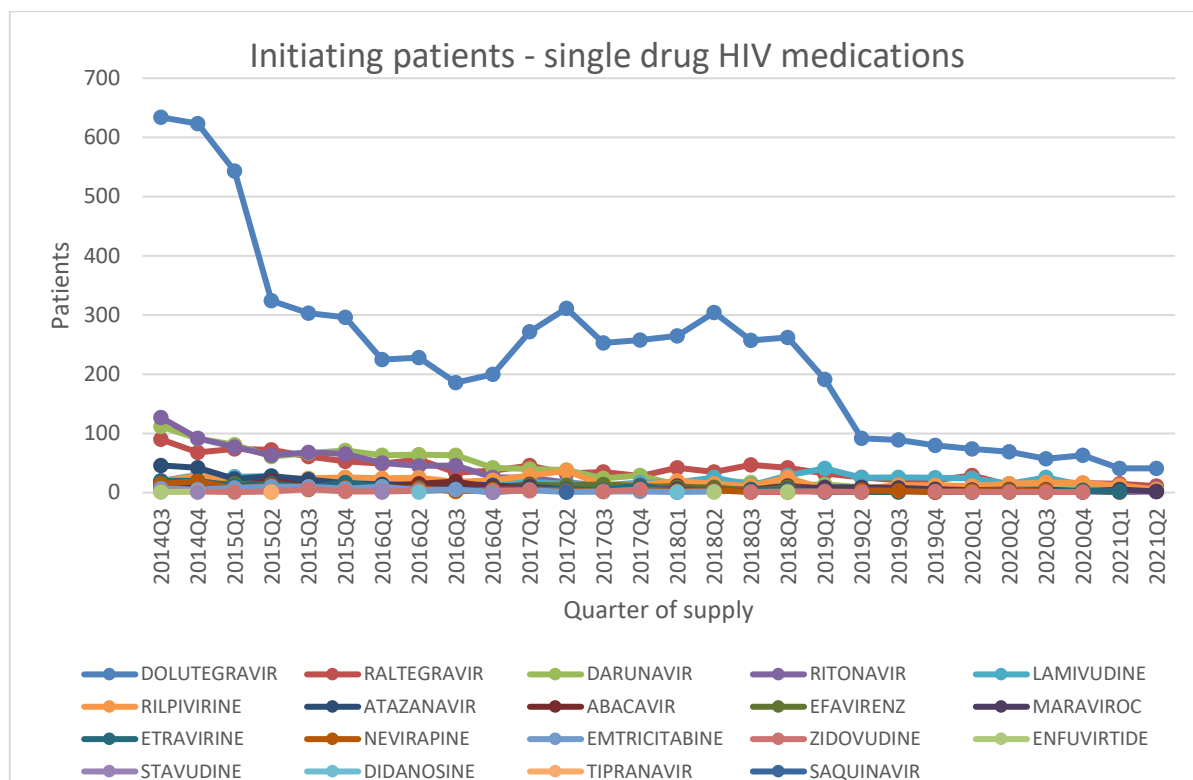


Figure 3b: Initiating patients receiving single HIV medication per quarter

Source: Services Australia prescriptions database, extracted August 2021

Figure 4a shows prevalent patients starting HIV combination therapy per quarter, while Figure 4b shows prevalent patients starting single drug HIV therapy per quarter.

Figure 4a shows the dramatic rise in the use of Biktarvy, which has become the highest use combination HIV therapy since its listing in March 2019.

Figure 4b shows that overall use of single drug HIV therapy has fallen since 2013. The use of dolutegravir was counter that of other single drug HIV therapy, as its utilisation (since its 2014 PBS listing) was on an upwards trajectory until the last quarter of 2018, when it began to fall.

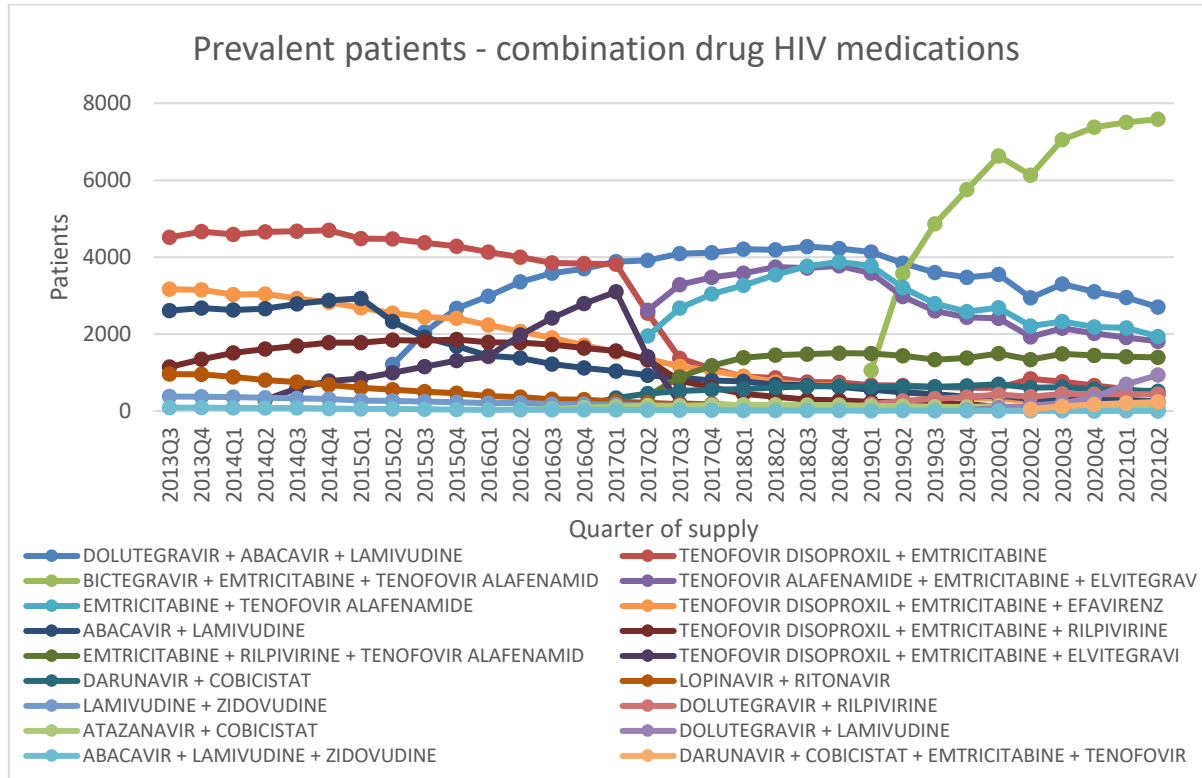


Figure 4a: Prevalent patients receiving combination HIV medication per quarter

Source: Services Australia prescriptions database, extracted August 2021

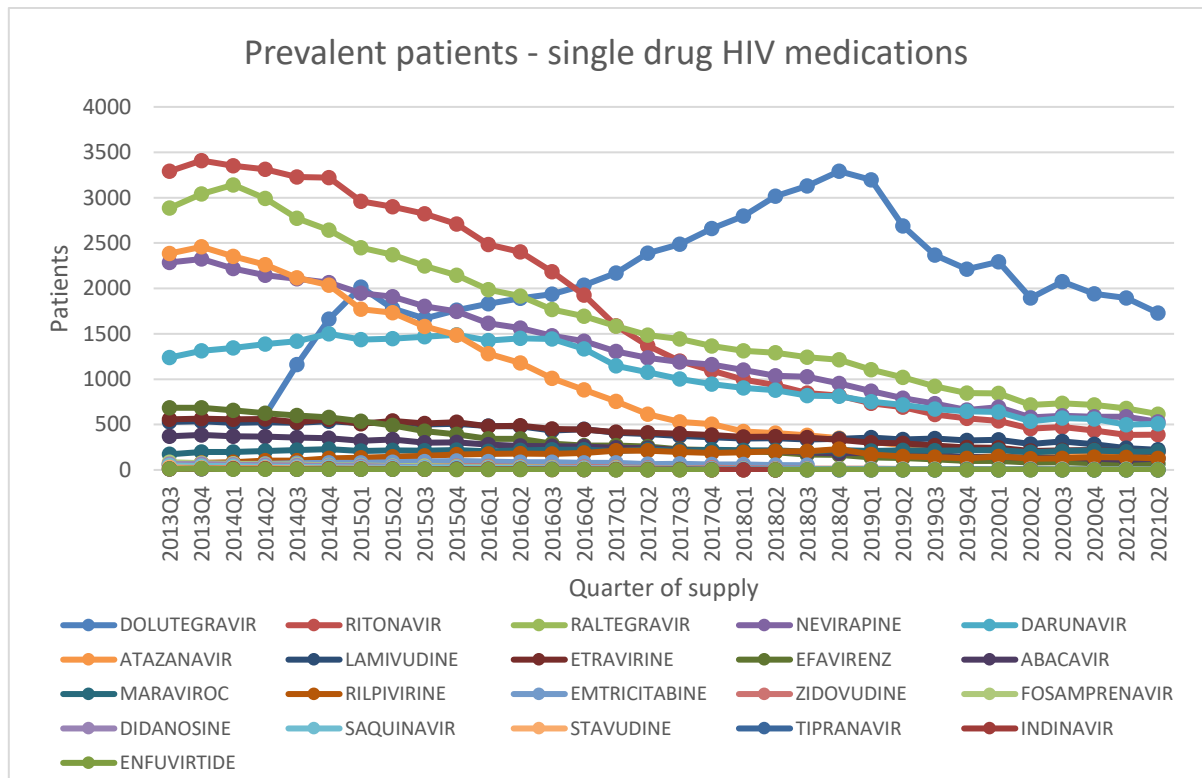


Figure 4b: Prevalent patients receiving single HIV medication per quarter

Source: Services Australia prescriptions database, extracted August 2021

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Figure 5 shows that government expenditure on HIV medications reached a peak in 2015 Q4 (if the COVID-19 effect is removed). Since the listing of Biktary on the PBS on 1 March 2019, total HIV medication expenditure has fallen slightly.

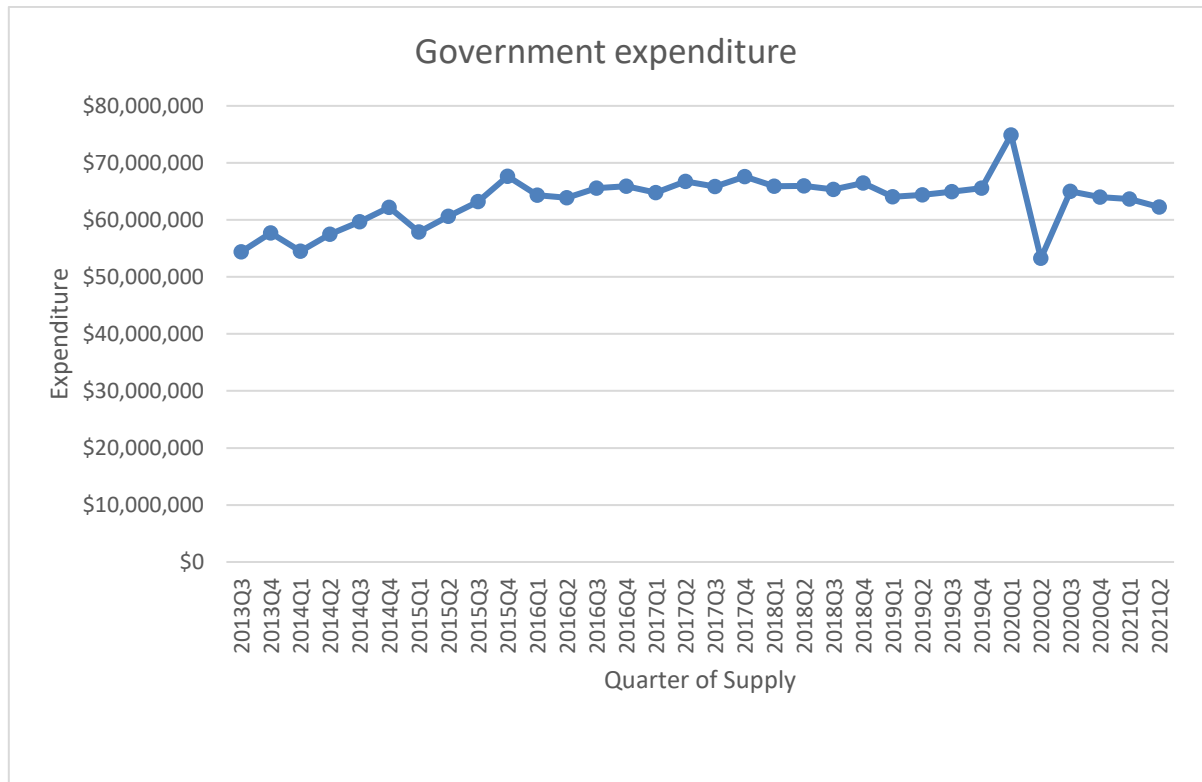


Figure 5a: Government expenditure on HIV medications per quarter

Source: Services Australia prescriptions database, extracted August 2021

Note: These figures do not include expenditure on PrEP

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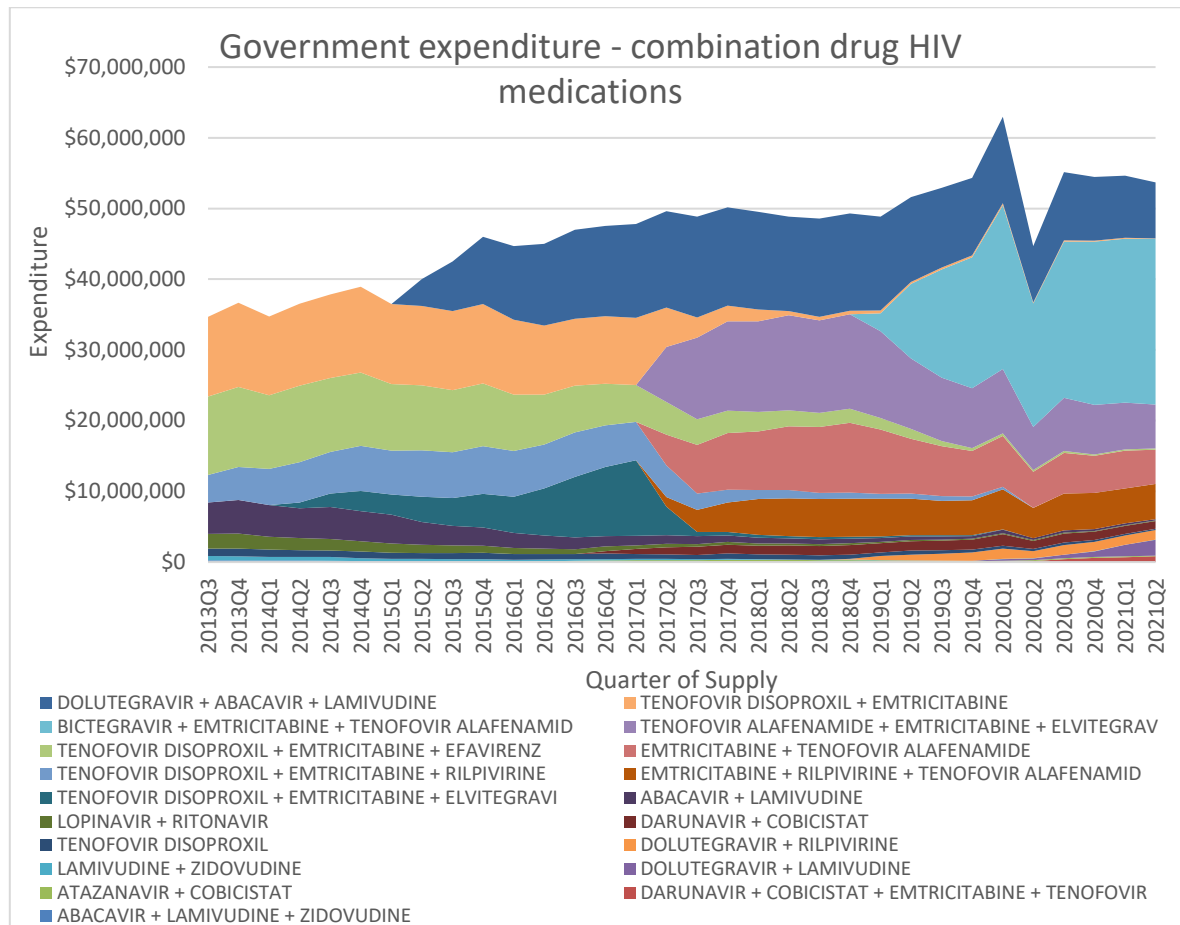


Figure 5b: Government expenditure on combination HIV medications per quarter

Source: Services Australia prescriptions database, extracted August 2021

Note: These figures do not include expenditure on PrEP

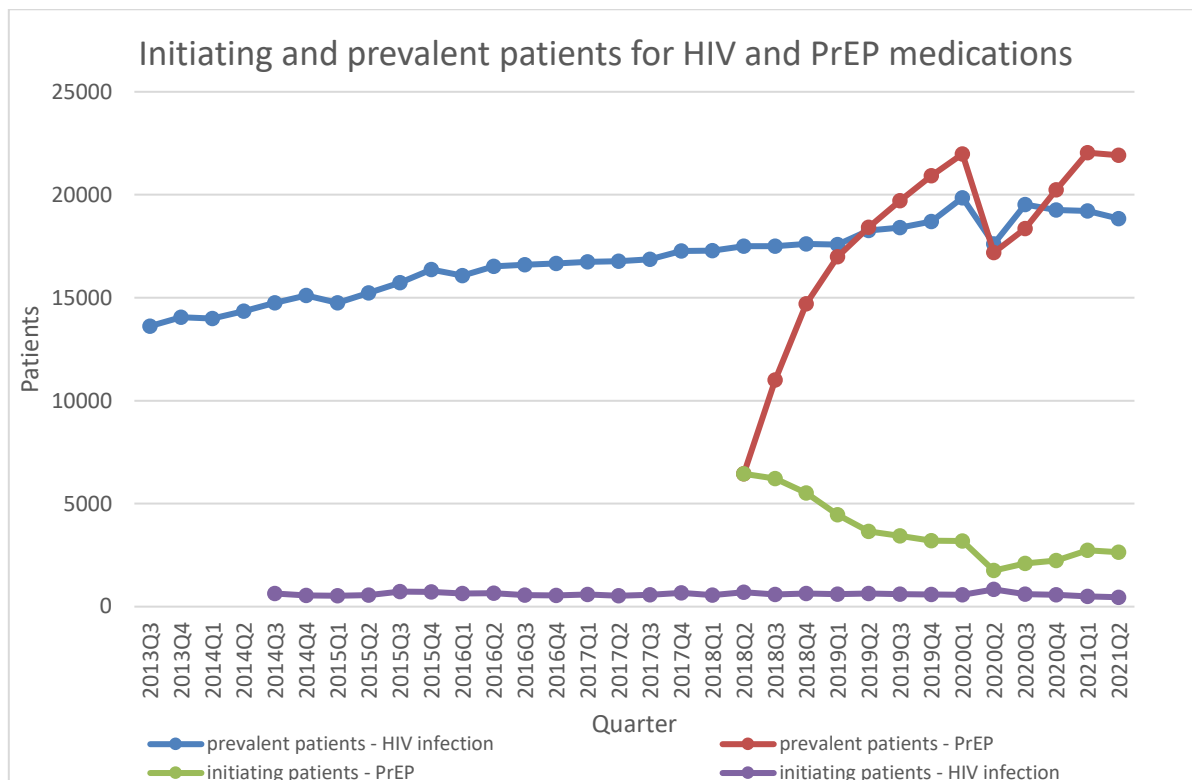


Figure 6: Initiating and prevalent patients for HIV and PrEP per quarter

Source: Services Australia prescriptions database, extracted August 2021

Note: prescribed PrEP medication is tenofovir disoproxil + emtricitabine

Table 4: Initiating and prevalent PrEP patients per year

Year	Prevalent patients	Initiating patients
2018	18,184	18,184
2019	29,813	14,751
2020	31,781	9,266

Figure 7 shows that the number of prescriptions for PrEP was increasing until the COVID-19 pandemic, when there was a significant drop between 2020 Q1 and 2020 Q2. Since 2020 Q2, this rate has started increasing, however it has not reached pre-COVID-19 levels.

Figure 8 shows that expenditure on PrEP has dropped significantly since its height in 2019 Q1.

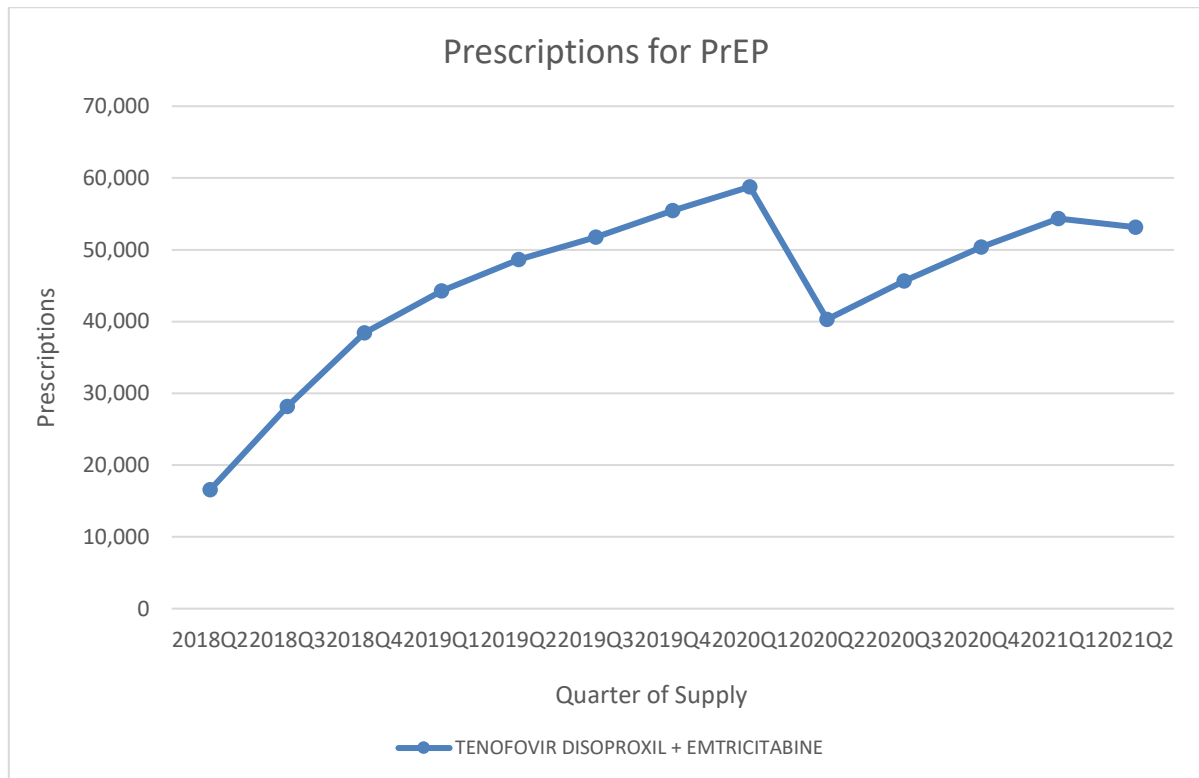


Figure 7: Total number of PBS/RPBS PrEP prescriptions supplied per quarter

Source: Services Australia prescriptions database, extracted August 2021

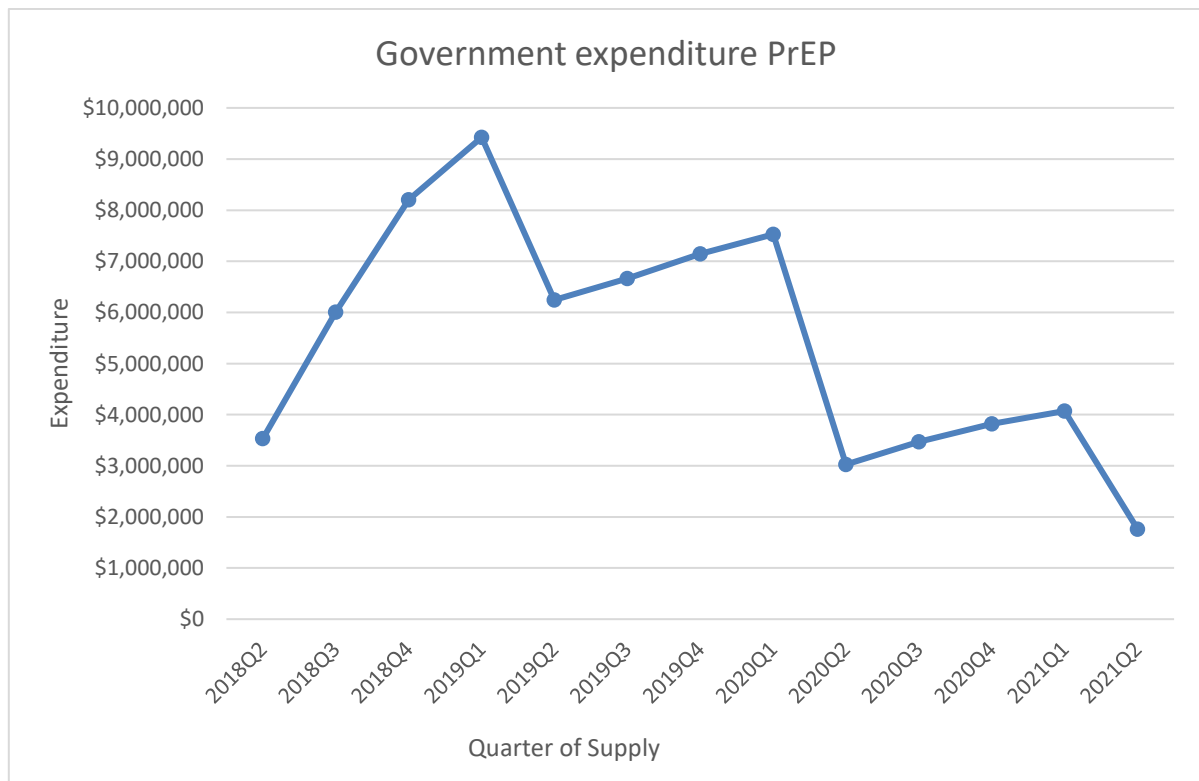


Figure 8: Government expenditure on PrEP medications per quarter

Source: Services Australia prescriptions database, extracted August 2021

Analysis of actual versus predicted utilisation

Dolutegravir + rilpivirine (DTG/RPV) (Juluca®)

A market share approach was used to inform the utilisation and financial estimates of Juluca, with the medication being cost-minimised against the individual components dolutegravir and rilpivirine (DTG+RPV; primary comparator) and a basket of comparators that references relevant alternative treatments (EVG/c/FTC/TAF, DTG+FTC/TAF, RPV/FTC/TAF, DTG/ABC/3TC, RAL+FTC/TAF, DTG+RPV).

Table 5 presents the predicted versus actual utilisation of Juluca. The results presented are based on the date of supply, which could lead to small differences when compared to the use of publicly available Services Australia data that is based on the date of processing data.

Table 5. Juluca: actual versus predicted utilisation

Parameter	Difference	Year 1 (Dec 2018 – Nov 2019)	Year 2 (Dec 2019 – Nov 2020)	Year 3 (Dec 2020 – Nov 2021)
Number of scripts dispensed	Predicted (P)	██████	██████	██████
	Actual (A)	1,971	3,037	Incomplete data
	Difference (%) ((P-A)/P) x 100	██████	██████	-
Drug cost (at published price), \$m	Predicted (P)	██████	██████	██████
	Actual (A)	\$3.29m	\$5.06m	Incomplete data
	Difference (%) ((P-A)/P) x 100	██████	██████	-

Since listing, the number of prescriptions dispensed for Juluca has been much lower than predicted, ██████ fold lower in the first year and ██████ fold lower in the second.

In the submission the sponsor estimated a net savings to the PBS of ██████ in year one of listing, and a net savings of ██████ in year two. Due to the lower than predicted uptake these savings might not have been realised.

Bictegravir with emtricitabine and tenofovir alafenamide (BIC/FTC/TAF)(Biktarvy®)

A market share approach was used to inform the utilisation and financial estimates of Biktarvy, with the listing being cost-minimised against dolutegravir/abacavir/ lamivudine (TRIUMEQ®).

Table 6 presents the predicted versus actual utilisation of Biktarvy. The results presented are based on the date of supply, which could lead to small differences between publicly available Services Australia data which is based on the date of processing.

Table 6. Biktarvy: actual versus predicted utilisation

Parameter	Difference	Year 1	Year 2	Year 3
Number of scripts dispensed	Predicted (P)	██████	██████	██████
	Actual (A)	34,082	49,036	Incomplete data
	Difference (%) ((P-A)/P) x 100	██████	██████	-
Drug cost (at published price), \$m	Predicted (P)*	██████	██████	██████
	Actual (A)	\$60.02m	\$87.15m	Incomplete data
	Difference (%) ((P-A)/P) x 100	██████	██████	-

Note: *The predicted cost = cost to R/PBS – co-payment costs

██████ listing, the number of prescriptions dispensed for Biktarvy has been ██████ than predicted, ██████ fold ██████ in the first year and ██████ fold ██████ in the second.

In the submission the sponsor estimated a net savings to the R/PBS of ██████ in year one of listing, and a net savings of ██████ in year two. Due to the ██████ than predicted uptake these savings might be greater than predicted, depending on the frequency of displaced medications and their cost.

Figure 9 shows the much higher number of prescriptions dispensed for Biktarvy compared to Juluca.

The number of prescriptions for Biktarvy increased each quarter from listing until the first quarter of 2020 where it dropped, most likely due to the influence of the COVID-19 pandemic. The number of prescriptions dispensed increased again from the second quarter, where it continued to increase each quarter, however at a much slower rate than the pre-COVID increases.

The prescription count of Juluca has largely remained steady since listing in December 2018.

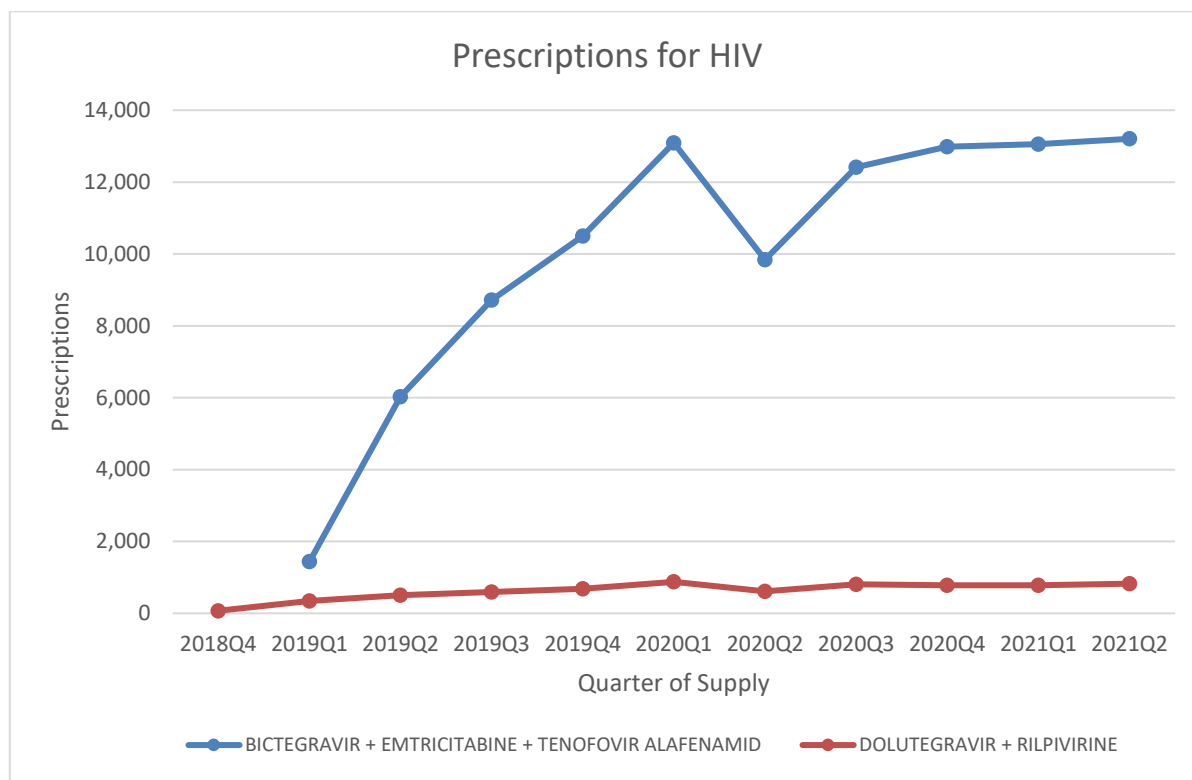


Figure 9: Number of prescriptions dispensed per quarter since listing of Biktarvy and Juluca on the R/PBS.

Source: Services Australia prescriptions database, extracted August 2021

Discussion

Since 2014 the overall number of HIV prescriptions has fallen. This is largely due to the reduction in prescribing rates of single drug HIV therapies. Whilst single drug prescription rates have fallen, prescriptions for combination drug regimens have increased, with Biktarvy becoming the most commonly prescribed HIV combination drug. Dolutegravir is the most commonly prescribed single drug HIV medication.

The number of initiating PrEP patients has fallen slightly since the listing of tenofovir disoproxil + emtricitabine on the PBS, while the number of prevalent patients has increased since listing. There was a reduction in utilisation between the first and second quarter of 2020, most likely due to the effect of the COVID-19 pandemic on social distancing practices in Australia. The utilisation of PrEP has since returned to its pre-COVID level.

The number of patients initiating HIV medication has remained at a consistent level over time, while the number of prevalent patients showed a steady climb until Q1 2020 when they dropped by 2,242 patients between Q1 2020 Q1 and Q2 2020 (Figure 5). Interestingly, the number of prevalent patients had almost returned to the pre-COVID level in Q3 2020, with 19,531 patients compared to 19,856 patients in Q1 2020. This number of prevalent patients fell slightly over Q4 2020 (19,266) and Q1 2021 (19,218).

Since listing on the PBS, Juluca's uptake has been [REDACTED] than what was predicted, whilst Biktarvy has had a [REDACTED] uptake than predicted. Both drugs were predicted to be cost saving for government expenditure on HIV listings. Growth in the expenditure on HIV listings has slowed since the listing of Biktarvy (Figure 5a).

Actions undertaken by the DUSC Secretariat

A copy of the report was provided to the sponsors of the HIV listings and relevant consumer groups.

DUSC Consideration

DUSC commented that the treatment options for HIV and PrEP have changed since the last DUSC review, and that there are multiple drug options to treat HIV.

DUSC noted:

- DUSC noted that prior to 2014, it was difficult to analyse the usage of HIV drugs as the Highly Specialised Drugs (HSD) supply was processed through a Services Australia bulk processing system which did not include patient level prescription data.
- DUSC noted that since 2012, new anti-retroviral therapy (ART) drugs have been introduced which has decreased pill burden, improved adverse drug event profiles, and increased effectiveness of treatment.
- The high level of initiators with new HIV drugs suggests a (non-PBS) drug familiarisation scheme or that prescribers are warehousing patients for when the new drugs are listed.
- There was a small group of prescribers, so a large proportion can shift quickly to new products.
- In 2015, treatment for all HIV-positive individuals changed to starting ART irrespective of CD4 cell count.
- In 2018, PrEP was added to the PBS.
- From 2015 to 2020 there has been a 24% increase in annual prevalence of ART and a 43% decrease in adverse reactions from ART 2016 (1742) to 2020 (1000). The introduction and development of ARTs had resulted in an increase in life expectancy with those who are living with HIV and decreased the morbidity associated with the disease.
- There has been a decrease in annual expenditure of combination and generics products from 2016 to 2020.
- There had been a decrease in single drug product prescriptions (likely as decreased preference for multi-pill ART contain dolutegravir) and an increase in combination product prescriptions.
- That the COVID-19 pandemic had likely impacted the prescription of HIV medication and patient care.

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- That a relatively small proportion of patients with HIV who had comorbidities had been prescribed ARTs with potential caution.
- That utilisation of dolutegravir+rilpivirine (Juluca) was less than expected, and the utilisation of bicitgravir + tenofovir alafenamide + emtricitabine (Biktarvy) was [REDACTED] than expected.
- That bicitgravir + tenofovir alafenamide + emtricitabine (Biktarvy) was not part of a risk share agreement, although the net cost of the drug had reduced costs on the PBS as it had replaced single HIV drugs taken in combination and had advantages over its competitors.
- That analyses of utilisation need to be cautious with rates of conversion from taking PrEP medication to HIV medication as neither dataset can inform about consumption.
- DUSC noted that Closing the Gap (CTG) rates should be considered with caution as patients have to agree to be identified as CTG and GPs may not re-enrol indigenous peoples into the CTG scheme.

DUSC Actions

DUSC requested that the report be provided to the PBAC for consideration.

Context for Analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

The sponsor's provided no comment.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

To the extent provided by law, DoH makes no warranties or representations as to accuracy or completeness of information contained in this report.

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Appendices

Appendix A: Summary of TGA approved indications

	Active ingredient(s)	Brand name	TGA registration
NRTIs	abacavir	Ziagen	Antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.
	abacavir + lamivudine	Kivexa	Antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age.
	abacavir + lamivudine + zidovudine	Trizivir	Antiretroviral therapy for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents over the age of 12 years. Trizivir should not be administered to adults and adolescents who weigh less than 40kg because it is a fixed dose tablet, and the dose cannot be adjusted for this patient population.
	emtricitabine	Emtriva	Treatment of HIV in combination with other antiretroviral agents in adults and paediatric patients 12 years of age and older, weighing more than 33 kg.
	emtricitabine + rilpivirine + tenofovir alafenamide	Odefsey	Treatment of HIV-1 infection in adults and adolescents (12 years and older with body weight at least 35 kg) with plasma HIV-1 RNA \leq 100,000 copies/mL at the start of therapy. The patients must not have a history of treatment failure or known mutations associated with resistance to the individual components of ODEFSEY.
	emtricitabine + tenofovir alafenamide	Descovy	Treatment of HIV-1 Infection: In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and paediatric patients weighing at least 25kg. The patients must not have a history of treatment failure or known mutations associated with resistance to the individual components of DESCOVY HIV-1 Pre-Exposure Prophylaxis: pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg, excluding individuals at risk from receptive vaginal sex.
	lamivudine	Zeffix, Zetlam	Zeffix (lamivudine) is indicated for the treatment of children (2 years and above), adolescent and adult patients with chronic hepatitis B and evidence of hepatitis B virus (HBV) replication. Children and adolescent also require evidence of active hepatic inflammation. The safety and efficacy of Zeffix (lamivudine) have not been established in patients with decompensated liver disease in placebo controlled studies. However, Zeffix (lamivudine) has

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	Active ingredient(s)	Brand name	TGA registration
			been shown to reduce HBV DNA levels prior to and post liver transplantation
	lamivudine + zidovudine	Combivir	For use alone or in combination with other antiretroviral therapies in the treatment of HIV infection.
	tenofovir disoproxil	Viread, Tenofovir Disoproxil Mylan, Tenofovir GH	Treatment in combination with other antiretroviral agents of HIV-infected adults and paediatric patients 12 years of age and older. Treatment of chronic hepatitis B in adults and treatment of chronic hepatitis B in paediatric patients 12 years of age and older with compensated liver disease and with evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels or evidence of active inflammation.
	tenofovir alafenamide + emtricitabine + elvitegravir + cobicistat	Genvoya	Single tablet regimen for the treatment of HIV-1 infection in adults and paediatric patients weighing at least 25 kg who are either treatment-naïve; or virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen. Patients must not have a history of treatment failure or known mutations associated with resistance to the antiretroviral components of GENVOYA.
	tenofovir disoproxil with emtricitabine	Tenofovir / Emtricitabine, Truvada	Treatment of HIV-1 infection for infected adults over the age of 18 years, in combination with other antiretroviral agents. Pre-Exposure Prophylaxis TRUVADA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.
	tenofovir disoproxil + emtricitabine + efavirenz	Atripla	Treatment of HIV infected adults over the age of 18 years.

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	Active ingredient(s)	Brand name	TGA registration
	zidovudine	Retrovir	Treatment of adult patients with severe symptomatic human immunodeficiency virus infection (AIDS or advanced AIDS related complex). Treatment of other HIV-positive adult patients with less than 500 CD4 cells/mm ³ . Combination therapy in advanced HIV infection: The addition of HIVID (zalcitabine) may be considered for the management of adult patients with advanced HIV infection and CD4 + cell counts less than or equal to 200/mm ³ , who have received Retrovir monotherapy for less than 12 months. Retrovir (zidovudine) is indicated for the treatment of HIV infection, alone and in combination with other antiretroviral therapies.
NNRTIs	efavirenz	Stocrin	For use in combination with other antiviral agents for the treatment of HIV-1 infection in adults and children.
	etravirine	Intelence	Treatment in combination with other antiretroviral agents of HIV-1 infection in antiretroviral treatment-experienced adults who have evidence of viral replication and resistance to Non-nucleoside Transcriptase Inhibitors and other antiretroviral agents. Treatment history of patients and genotypic testing should be performed to guide the use of etravirine.
	nevirapine	Nevirapine, Viramune, Viramune XR	Immediate-release tablets and oral suspension in combination with antiretroviral agents is indicated for the treatment of HIV-1 infection in adults and children over the age of 2 months. Extended-release tablets in combination with antiretroviral agents is indicated for the treatment of HIV-1 infection in adults and children over the age of three years. Extended-release tablets are not suitable for the 14 day lead-in period for patients starting nevirapine. Other nevirapine formulations, such as immediate-release tablets or oral suspension should be used. Resistant virus emerges rapidly when administered as monotherapy or in dual combination therapy with an antiretroviral agent. Therefore, it should always be administered in combination with at least two additional antiretroviral agents.
	rilpivirine	Edurant	Treatment in combination with other antiretroviral medicinal products of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with viral load less than or equal to 100,000 copies/mL at baseline.
HIV-PIs	atazanavir	Reyataz	Treatment of HIV 1 infection, in combination with other antiretroviral agents
	atazanavir + cobicistat	Evotaz	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults

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	Active ingredient(s)	Brand name	TGA registration
	darunavir	Prezista	Treatment (with low dose ritonavir as a pharmacokinetic enhancer) in combination with other antiretroviral agents of human immunodeficiency virus-1 (HIV-1) infection in adult patients. Treatment (with low dose ritonavir as a pharmacokinetic enhancer) in combination with other antiretroviral agents of human immunodeficiency virus (HIV) infection in treatment-experienced paediatric patients aged 6 years and older, weighing at least 20 kg.
	darunavir + cobicistat	Prezcobix	Treatment in combination with other antiretroviral agents of adult patients with human immunodeficiency virus-1 (HIV-1) infection in: antiretroviral treatment-naive patients, antiretroviral treatment-experienced patients with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/ml, or antiretroviral treatment-experienced but HIV protease inhibitor-naive patients for whom HIV-1 genotype testing is unavailable
	darunavir + cobicistat + emtricitabine + tenofovir alafenamide	Symtuza	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg). Genotypic testing should guide the use of SYMTUZA
	fosamprenavir	Telzir	Treatment, in combination with low dose ritonavir, of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults, adolescents and children of 6 years and above in combination with other antiretroviral medicinal products.
	lopinavir + ritonavir	Kaletra	Treatment of HIV-1 infection, in combination with other antiretroviral agents in adults and children aged 2 years and older.
	ritonavir	Norvir	Use in combination with appropriate antiretroviral agents or as monotherapy if combination therapy is inappropriate, for the treatment of HIV-1 infection in adults and children aged 12 years and older.
	saquinavir	Invirase	Treatment of HIV/AIDS in adults and children 12 years of age or older. Clinical studies indicate that saquinavir should only be used in combination with ritonavir and other anti-retroviral therapies.
	tipranavir	Aptivus	For combination treatment, co-administered with low dose ritonavir, of HIV infection in antiretroviral treatment experienced adults and adolescents aged 12 years and older, with evidence of viral replication, who have HIV-1 strains resistant to more than one protease inhibitor. In deciding to initiate therapy with APTIVUS/ritonavir, careful consideration should be given to treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic testing should be performed to guide the use of APTIVUS.

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	Active ingredient(s)	Brand name	TGA registration
INSTIs	bictegravir + emtricitabine + tenofovir alafenamide	Biktarvy	BIKTARVY is indicated for the treatment of HIV-1 infection in adults and paediatric patients weighing at least 25 kg who are antiretroviral therapy (ART)-naïve or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen at the start of therapy with no history of treatment failure, and no known substitutions associated with resistance to the individual components of BIKTARVY.
	dolutegravir	Tivicay	Treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in adults and children over 6 years of age.
	dolutegravir + abacavir + lamivudine	Triumeq	Treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age who are antiretroviral treatment-naïve or are infected with HIV without documented or clinically suspected resistance to any of the three antiretroviral agents (dolutegravir, abacavir or lamivudine) in TRIUMEQ.
	dolutegravir + lamivudine	Dovato	Treatment of Human Immunodeficiency Virus-1 (HIV-1) infection in adults and adolescents (from 12 years of age weighing at least 40kg): in antiretroviral treatment-naïve patients with no antiretroviral treatment history who have no known or suspected resistance to either antiretroviral component; or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to the integrase inhibitor class or lamivudine.
	dolutegravir with rilpivirine	Juluca	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor or integrase inhibitor.
	raltegravir	Isentress	Treatment in combination with other antiretroviral agents of human immunodeficiency virus (HIV-1) infection in adults, adolescents and children from the age of 2 years.
		enfuvirtide	Fuzeon

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	Active ingredient(s)	Brand name	TGA registration
	maraviroc	Celsentri	Treatment in combination with other antiretroviral medicinal products of adult patients infected with only CCR5-tropic HIV-1. The use of other active agents with CELSENTRI is associated with a greater likelihood of treatment response.

Appendix B: Dosage and frequency of administration for antiretroviral HIV medicines⁹

	Active ingredient(s)	Brand name	Adult dose for patients without comorbidities
NRTIs	abacavir	Ziagen	Oral, 300 mg twice daily or 600 mg once daily.
	abacavir + lamivudine	Kivexa	1 tablet (abacavir 600 mg, lamivudine 300 mg) daily.
	abacavir + lamivudine + zidovudine	Trizivir	1 tablet (abacavir 300 mg, lamivudine 150 mg, zidovudine 300 mg) daily.
	emtricitabine	Emtriva	200 mg once daily.
	emtricitabine + rilpivirine + tenofovir alafenamide	Odefsey	1 tablet once (emtricitabine 200 mg, rilpivirine 25 mg, tenofovir alafenamide 25 mg) daily with food.
	emtricitabine + tenofovir alafenamide	Descovy	1 tablet once (emtricitabine 200 mg, tenofovir alafenamide 25 mg) daily with food OR with combinations of atazanavir or darunavir (boosted with either ritonavir or cobicistat) or lopinavir/ritonavir, 1 tablet (emtricitabine 200 mg, tenofovir alafenamide 10 mg) once daily.
	lamivudine	Zeffix, Zetlam	Oral, 100 mg once daily.
	lamivudine + zidovudine	Combivir	1 tablet (lamivudine 150 mg, zidovudine 300 mg) twice daily.
	tenofovir disoproxil	Viread, Tenofovir Disoproxil Mylan, Tenofovir GH	1 tablet once daily with food.
	tenofovir alafenamide + emtricitabine + elvitegravir + cobicistat	Genvoya	1 tablet (tenofovir alafenamide fumarate 10 mg, emtricitabine 200 mg, elvitegravir 150 mg, cobicistat 150 mg) once daily with food.
	tenofovir disoproxil with emtricitabine	Tenofovir/Emtricitabine, Truvada	1 tablet (tenofovir disoproxil 300 mg, emtricitabine 200 mg) once daily with food.
	tenofovir disoproxil + emtricitabine + efavirenz	Atripla	1 tablet (tenofovir disoproxil 300 mg, emtricitabine 200 mg, efavirenz 600 mg) once daily.
	zidovudine	Retrovir	Oral, 250–300 mg twice daily.
NNRTIs	efavirenz	Stocrin	Oral, 600 mg once daily. With voriconazole, 300 mg once daily.
	etravirine	Intelence	Oral, 200 mg twice daily after food.
	nevirapine	Nevirapine, Viramune, Viramune XR	Initial dose: Conventional tablet, oral liquid, 200 mg once daily for 14 days. Maintenance dose: Conventional tablet, oral liquid, 200 mg twice daily. Controlled release tablet, 400 mg once daily.
	rilpivirine	Edurant	Oral, 25 mg once daily. With rifabutin, oral 50 mg once daily.

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	Active ingredient(s)	Brand name	Adult dose for patients without comorbidities
HIV-PIs	atazanavir	Reyataz	Treatment-naïve: Oral, 300 mg atazanavir (with 100 mg ritonavir) once daily or 400 mg atazanavir once daily. With efavirenz, 400 mg atazanavir (with 100 mg ritonavir) once daily. With tenofovir disoproxil, 300 mg atazanavir (with 100 mg ritonavir) once daily. Treatment-experienced: 300 mg atazanavir (with 100 mg ritonavir) once daily.
	atazanavir + cobicistat	Evotaz	1 tablet (atazanavir 300 mg, cobicistat 150 mg) once daily.
	darunavir	Prezista	No darunavir resistance substitutions and viral load <100 000 copies/mL; or HIV-PI naïve when genotype testing is not available, oral 800 mg (with 100 mg ritonavir) once daily. Darunavir resistance substitutions or viral load >100 000 copies/mL; or HIV-PI experienced when genotype testing is not available, oral 600 mg (with 100 mg ritonavir) twice daily.
	darunavir + cobicistat	Prezcobix	1 tablet (darunavir 800 mg, cobicistat 150 mg) once daily with food.
	darunavir + cobicistat + emtricitabine + tenofovir alafenamide	Symtuza	1 tablet (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg, tenofovir alafenamide 10 mg) once daily with food.
	fosamprenavir	Telzir	No previous antiretroviral treatment, oral 1400 mg (with 200 mg ritonavir) once daily or 700 mg (with 100 mg ritonavir) twice daily. Previous HIV-PI treatment, oral 700 mg (with 100 mg ritonavir) twice daily.
	lopinavir + ritonavir	Kaletra	Treatment-naïve: Oral, 400/100 mg twice daily or 800/200 mg once daily (lopinavir 100 mg, ritonavir 25/50 mg) . With efavirenz, nevirapine, carbamazepine, phenytoin or phenobarbital, oral 400/100 mg twice daily. Treatment-experienced: Oral, 400/100 mg twice daily. With efavirenz, nevirapine, oral 500/125 mg twice daily if decreased susceptibility to lopinavir is suspected.
	ritonavir	Norvir	Low-dose ritonavir regimens: With atazanavir, darunavir (treatment-naïve), oral 100 mg once daily. With darunavir (treatment-experienced) or saquinavir, oral 100 mg twice daily. With fosamprenavir twice daily regimen, oral 100 mg twice daily. With fosamprenavir once daily regimen, oral 200 mg once daily. With tipranavir, oral 200 mg twice daily.
	saquinavir	Invirase	Treatment-naïve: Oral, 500 mg (with 100 mg ritonavir) twice a day for 7 days, then increase to 1000 mg (with 100 mg ritonavir) twice a day. Treatment-experienced: Use for patients switching from another HIV-PI with ritonavir or from a NNRTI (except rilpivirine). Oral, 1000 mg (with 100 mg ritonavir) twice a day
	tipranavir	Aptivus	Oral, 500 mg (with 200 mg ritonavir) twice daily.

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	Active ingredient(s)	Brand name	Adult dose for patients without comorbidities
INSTIs	bictegravir + emtricitabine + tenofovir alafenamide	Biktarvy	1 tablet (bictegravir 50 mg, emtricitabine 200 mg, tenofovir alafenamide fumarate 25 mg) once daily.
	dolutegravir	Tivicay	Oral, 50 mg once daily.
	dolutegravir + abacavir + lamivudine	Triumeq	1 tablet (dolutegravir 50 mg, abacavir 600 mg, lamivudine 300 mg) once daily.
	dolutegravir + lamivudine	Dovato	1 tablet (dolutegravir 50 mg, lamivudine 300 mg) once daily.
	dolutegravir with rilpivirine	Juluca	1 tablet (dolutegravir 50 mg, rilpivirine 25 mg) once daily with a meal.
	raltegravir	Isentress	400 mg tablet: oral 400 mg twice daily. 600 mg tablet: Do not use for treatment-experienced patients unless virologically suppressed on initial regimen of raltegravir 400 mg twice daily. Oral, 1200 mg once daily.
	enfuvirtide	Fuzeon	subcutaneous, 90 mg twice daily.
	maraviroc	Celsentri	Oral, 300 mg twice daily. With nevirapine or tipranavir/ritonavir, oral 300 mg twice daily. With strong CYP3A4 inhibitors (with or without a CYP3A4 inducer), eg clarithromycin, HIV-PIs (except tipranavir/ritonavir), elvitegravir with cobicistat, itraconazole, oral 150 mg twice daily. With CYP3A4 inducers (without a strong CYP3A4 inhibitor), eg efavirenz, etravirine, rifampicin, carbamazepine, phenytoin, oral 600 mg twice daily.

Appendix C: HIV medications and strength

Prescriptions				
INDICATION2	drug_name	item_code	form_str	Total
HIV infection	ABACAVIR	05601T	Tablet 300 mg (as sulfate)	5,027
		05602W	Oral solution 20 mg (as sulfate) per mL, 240 mL	124
		06264Q	Tablet 300 mg (as sulfate)	29
		10294T	Tablet 300 mg (as sulfate)	8,403
		10356C	Oral solution 20 mg (as sulfate) per mL, 240 mL	271
	ABACAVIR + LAMIVUDINE	05603X	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	37,243
		06458X	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	61
		10357D	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	32,528
		11246X	Tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg	1,438
	ABACAVIR + LAMIVUDINE + ZIDOVUDINE	05604Y	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	1,062
		10305J	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	689
	ACICLOVIR	08234J	Tablet 800 mg	533
	ATAZANAVIR	05612J	Capsule 300 mg (as sulfate)	24,870
		05613K	Capsule 150 mg (as sulfate)	233
		05614L	Capsule 200 mg (as sulfate)	4,500
		06452N	Capsule 200 mg (as sulfate)	20
		09614B	Capsule 300 mg (as sulfate)	54
		10276W	Capsule 150 mg (as sulfate)	159
		10321F	Capsule 300 mg (as sulfate)	17,706
		10349Q	Capsule 200 mg (as sulfate)	5,061
		11657M	Capsule 300 mg (as sulfate)	450
	ATAZANAVIR + COBICISTAT	10692R	Tablet containing 300 mg atazanavir and 150 mg cobicistat	4,358
	BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMID	11649D	Tablet containing bicitgravir 50 mg with emtricitabine 200 mg with tenofovir alafenamide 25 mg	101,282
	DARUNAVIR	02980W	Tablet 800 mg (as ethanolate)	7,368
		03392M	Tablet 600 mg (as ethanolate)	9,015
		05000E	Tablet 600 mg (as ethanolate)	6
		05821J	Tablet 400 mg (as ethanolate)	1,985
		05823L	Tablet 400 mg (as ethanolate)	8
		10000H	Tablet 800 mg (as ethanolate)	11
		10287K	Tablet 150 mg (as ethanolate)	34
		10329P	Tablet 600 mg (as ethanolate)	15,562

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		10367P	Tablet 800 mg (as ethanolate)	23,187
	DARUNAVIR + COBICISTAT	10903W	Tablet containing darunavir 800 mg with cobicistat 150 mg	18,607
	DARUNAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR	11955F	Tablet containing darunavir 800 mg with cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg	1,339
	DIDANOSINE	05663C	Capsule 125 mg (containing enteric coated beadlets)	6
		05665E	Capsule 250 mg (containing enteric coated beadlets)	187
		05666F	Capsule 400 mg (containing enteric coated beadlets)	476
		06301P	Capsule 400 mg (containing enteric coated beadlets)	6
		10313T	Capsule 400 mg (containing enteric coated beadlets)	240
		10364L	Capsule 250 mg (containing enteric coated beadlets)	91
	DOLUTEGRAVIR	10283F	Tablet 50 mg (as sodium)	100,078
		10065R	Tablet 50 mg (as sodium)	12,158
		10070B	Tablet 50 mg (as sodium)	28
	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE	10247H	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	1,884
		10248J	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	≤5
		10345L	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	153,937
	DOLUTEGRAVIR + LAMIVUDINE	11843H	Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg	4,139
	DOLUTEGRAVIR + RILPIVIRINE	11540J	Tablet containing dolutegravir 50 mg (as sodium) with rilpivirine 25 mg (as hydrochloride)	6,895
	EFAVIRENZ	05706H	Tablet 600 mg	8,154
		05707J	Oral solution 30 mg per mL, 180 mL	51
		05708K	Tablet 200 mg	255
		06356M	Tablet 600 mg	129
		06372J	Oral solution 30 mg per mL, 180 mL	≤5
		10275T	Oral solution 30 mg per mL, 180 mL	16
		10336B	Tablet 200 mg	326
		10366N	Tablet 600 mg	7,963
	EMTRICITABINE	05709L	Capsule 200 mg	950
		10274R	Capsule 200 mg	1,668
	EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMID	11104K	Tablet containing emtricitabine 200 mg with rilpivirine 25 mg with tenofovir alafenamide 25 mg	42,750

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	EMTRICITABINE + TENOFOVIR ALAFENAMIDE	11099E	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 10 mg	13,901
		11113X	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 25 mg	72,642
	ENFUVRTIDE	05710M	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	122
		10365M	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	159
	ETRAVIRINE	05062K	Tablet 200 mg	7
		05084N	Tablet 200 mg	7,151
		10301E	Tablet 200 mg	14,389
	FAMCICLOVIR	08896F	Tablet 500 mg	4,755
	FOSAMPRENAVIR	05746K	Tablet 700 mg (as calcium)	852
		10337C	Tablet 700 mg (as calcium)	594
	GANCICLOVIR	10328N	Powder for I.V. infusion 500 mg (as sodium)	106
	INDINAVIR	05752R	Capsule 400 mg (as sulfate)	151
		10363K	Capsule 400 mg (as sulfate)	89
	LAMIVUDINE	05772T	Tablet 150 mg	2,233
		05773W	Oral solution 10 mg per mL, 240 mL	234
		05774X	Tablet 300 mg	4,586
		06193Y	Tablet 150 mg	16
		06194B	Oral solution 10 mg per mL, 240 mL	≤5
		06435Q	Tablet 300 mg	≤5
		10311Q	Tablet 300 mg	10,538
		10320E	Oral solution 10 mg per mL, 240 mL	689
		10348P	Tablet 150 mg	4,034
	LAMIVUDINE + ZIDOVUDINE	05775Y	Tablet 150 mg-300 mg	4,324
		06234D	Tablet 150 mg-300 mg	104
		10284G	Tablet 150 mg-300 mg	5,060
	LOPINAVIR + RITONAVIR	05789Q	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	133
		05790R	Tablet 100 mg-25 mg	187
		05791T	Tablet 200 mg-50 mg	9,947
		06341R	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	≤5
		06495W	Tablet 200 mg-50 mg	125
		09633B	Tablet 100 mg-25 mg	11
		10272P	Tablet 200 mg-50 mg	6,809
		10285H	Tablet 100 mg-25 mg	227
		10327M	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	354

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	MARAVIROC	05792W	Tablet 150 mg	1,489
		05793X	Tablet 300 mg	1,336
		10318C	Tablet 150 mg	3,698
		10355B	Tablet 300 mg	5,509
	NEVIRAPINE	01129K	Tablet 400 mg (extended release)	89
		01132N	Tablet 400 mg (extended release)	26,272
		06215D	Tablet 200 mg	152
		09506H	Tablet 200 mg	4,356
		09507J	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	36
		10303G	Tablet 400 mg (extended release)	42,894
		10304H	Tablet 200 mg	4,181
		10319D	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	54
	RALTEGRAVIR	10286J	Tablet 400 mg (as potassium)	47,810
		10299C	Tablet 25 mg (as potassium)	15
		10326L	Tablet 100 mg (as potassium)	113
		11248B	Tablet 600 mg (as potassium)	6,360
		02760G	Tablet 100 mg (as potassium)	25
		09523F	Tablet 400 mg (as potassium)	37,378
		09629T	Tablet 400 mg (as potassium)	110
	RILPIVIRINE	01173R	Tablet 25 mg (as hydrochloride)	1,339
		10298B	Tablet 25 mg (as hydrochloride)	7,276
	RITONAVIR	09542F	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	45
		09660K	Tablet 100 mg	42,853
		09677H	Tablet 100 mg	72
		10273Q	Tablet 100 mg	48,603
		10300D	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	63
	SAQUINAVIR	06498B	Tablet 500 mg (as mesilate)	12
		09545J	Tablet 500 mg (as mesilate)	458
		10335Y	Tablet 500 mg (as mesilate)	391
	STAVUDINE	09554W	Capsule 30 mg	46
		09556Y	Capsule 40 mg	183
		10271N	Capsule 30 mg	22
		10312R	Capsule 40 mg	100
	TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAV	11114Y	Tablet containing tenofovir alafenamide 10 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	88,057
	TENOFOVIR DISOPROXIL	06358P	Tablet containing tenofovir disoproxil fumarate 300 mg	579
		09563H	Tablet containing tenofovir disoproxil fumarate 300 mg	7,780
		10310P	Tablet containing tenofovir disoproxil fumarate 300 mg	15,459

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		11142K	Tablet containing tenofovir disoproxil phosphate 291 mg	1,270
		11155D	Tablet containing tenofovir disoproxil maleate 300 mg	1,134
	TENOFOVIR DISOPROXIL + EMTRICITABINE	10946D	Tablet containing tenofovir alafenamide 10 mg with emtricitabine 200 mg	790
		10966E	Tablet containing tenofovir alafenamide 25 mg with emtricitabine 200 mg	3,545
		06468K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	458
		09564J	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	63,121
		10347N	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	60,351
		11146P	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	3,706
		11149T	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	5,554
		12506F	Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg	≤5
	TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ	09565K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	41,027
		09650X	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	605
		10297Y	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	41,547
		11732L	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	1,431
	TENOFOVIR DISOPROXIL + EMTRICITABINE + ELVITEGRAVI	10085T	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	25
		10088Y	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	5,973
		10307L	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	13,066
		10680D	Tablet containing tenofovir alafenamide 10 mg with emtricitabine 200 mg,	16,402

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			elvitegravir 150 mg and cobicistat 150 mg	
	TENOFOVIR DISOPROXIL + EMTRICITABINE + RILPIVIRINE	01490K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	38
		01491L	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	22,835
		10314W	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	31,576
	TIPRANAVIR	09567M	Capsule 250 mg	120
		10344K	Capsule 250 mg	139
	VALGANCICLOVIR	10277X	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	263
		10306K	Tablet 450 mg (as hydrochloride)	7,216
	ZIDOVUDINE	09570Q	Syrup 10 mg per mL, 200 mL	49
		09651Y	Capsule 100 mg	122
		09652B	Capsule 250 mg	442
		10266H	Capsule 100 mg	90
		10360G	Capsule 250 mg	556
		10361H	Syrup 10 mg per mL, 200 mL	107
PrEP	TENOFOVIR DISOPROXIL + EMTRICITABINE	11276L	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	259,833
		11296M	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	282,055
		11306C	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	43,789
		12542D	Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg	198
Chronic hepatitis B infection	TENOFOVIR DISOPROXIL	06358P	Tablet containing tenofovir disoproxil fumarate 300 mg	21,796
		09563H	Tablet containing tenofovir disoproxil fumarate 300 mg	27,425
		10310P	Tablet containing tenofovir disoproxil fumarate 300 mg	182,053
		11142K	Tablet containing tenofovir disoproxil phosphate 291 mg	19,824
		11155D	Tablet containing tenofovir disoproxil maleate 300 mg	20,621
Herpes	FAMCICLOVIR	08896F	Tablet 500 mg	22,012
Herpes zoster	FAMCICLOVIR	08896F	Tablet 500 mg	≤5
Recurrent moderate to	FAMCICLOVIR	08896F	Tablet 500 mg	49,447

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severe genital herpes				
Recurrent moderate to severe oral or labial herpes	FAMCICLOVIR	08896F	Tablet 500 mg	24,927
(blank)	FAMCICLOVIR	08896F	Tablet 500 mg	390
	TENOFOVIR DISOPROXIL	06358P	Tablet containing tenofovir disoproxil fumarate 300 mg	2,251
		09563H	Tablet containing tenofovir disoproxil fumarate 300 mg	9
		10310P	Tablet containing tenofovir disoproxil fumarate 300 mg	517
		11142K	Tablet containing tenofovir disoproxil phosphate 291 mg	32
		11155D	Tablet containing tenofovir disoproxil maleate 300 mg	11
Grand Total				2,506,125
			Highlighted items indication was determined by restriction code.	
			Unknown restriction (blank) may be HIV or Other (Herpes or Hep B)	