

HIV antiretroviral medicines: Utilisation analysis using PBS data

Drug utilisation sub-committee (DUSC)

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Abstract

Purpose

DUSC requested a review of the utilisation of antiretroviral medicines used for the treatment of Human Immunodeficiency Virus (HIV) and for pre-exposure prophylaxis (PrEP) of HIV at its June 2021 meeting. The analyses in this report are for the antiretroviral medicines used to treat HIV and are based on PBS data.

Antiretroviral medicines may also be called antiretroviral therapies or ART.

Data Source / methodology

Data for all medicines used for the treatment of HIV antiretroviral medicines listed on the PBS were extracted from the Services Australia PBS supplied prescriptions database from January 2013 to December 2020.

Key Findings

- Between 2016 and 2020, the number of antiretrovirals dispensed on the PBS has been stable at approximately 130,000 prescriptions per year. Government expenditure on antiretroviral medicines in 2020 was \$216.9 million, down from \$221.4 million in 2016.
- The combination antiretroviral medicines incorporate different classes of antiretrovirals within a single tablet. They are the class of antiretrovirals most commonly dispensed and most costly for government. Their use continues to increase thanks to a rapid uptake of bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy) since its listing in March 2019. In 2020 bictegravir + tenofovir alafenamide + emtricitabine was dispensed 37,681 times accounting for 29.1% of all antiretroviral prescriptions that year and \$74.1 million or 34.1% of all government expenditure.
- In 2020, 23,179 patients were dispensed at least one antiretroviral medicine. This is a 24% increase in the number of patients dispensed antiretrovirals since 2015.
- The number of patients using combination antiretrovirals has increased year on year while the number of patients using other classes of antiretrovirals has fallen. In 2020, there were:
 - 18,859 patients dispensed combination antiretrovirals;
 - 4843 patients dispensed nucleoside and nucleotide reverse transcriptase inhibitor (NRTIs);

- 3847 patients dispensed integrase strand transfer inhibitors (INSTIs);
- 2070 patients dispensed HIV protease inhibitors (HIV-PIs);
- 688 patients dispensed non-nucleoside reverse transcriptase inhibitors (NNRTIs); and
- 263 patients dispensed entry inhibitors.
- The most commonly used individual antiretroviral medicines in 2020 were:
 - bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy; combination antiretroviral) dispensed to 9119 patients;
 - abacavir + dolutegravir + lamivudine (Triumeq; combination antiretroviral) dispensed to 4423 patients;
 - emtricitabine + tenofovir alafenamide (Descovy; NRTI) dispensed to 3292 patients; and
 - elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya; combination antiretroviral) dispensed to 2970 patients.
- Since 2016, the number of patients newly started on antiretrovirals each year has fallen from 1742 patients to 1000 patients in 2020, in line with the decreasing incidence of HIV notifications in Australia.
- Patients newly starting antiretroviral medicines are predominately dispensed combination antiretrovirals. In 2020, the combination antiretroviral that the most patients were started on was bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy). There were 623 patients started on this medicine which was 62.3% of all patients newly started on antiretrovirals in 2020.
- The majority of patients dispensed antiretroviral medicines are male and living in major cities. Approximately half are aged 50 years or older.
- In 2020, 1.1% of patients dispensed an antiretroviral medicine had a CTG indicator, identifying them as being an Aboriginal or Torres Strait Islander.
- This study found no evidence that dispensing of antiretroviral medicines had been affected by the COVID-19 pandemic during 2020.
- There were 1653 patients, or 7.1% of patients dispensed at least one antiretroviral during 2018 and 2019, who were dispensed regimens containing two NRTIs. Australian guidelines note that this regimen should not be offered at any time.
- There were a small numbers of patients who were dispensed non-HIV medicines which are contraindicated or to be used with caution in people taking some antiretroviral medicines.

Purpose of analysis

At its June 2021 meeting, DUSC requested a review of antiretroviral medicines for the treatment or prevention of HIV. DUSC noted that the previous review of these medicines had been conducted in 2013. Since this time there have been a number of changes including:

- PBS restrictions limiting the use of antiretroviral medicines to patients with CD4+ counts^a of less than 500 cells/mm³ or symptomatic HIV disease were removed in late 2013;¹
- the addition of new antiretroviral medicines and new combination regimens to treat HIV to the PBS. DUSC noted substantial growth in the utilisation of some of the newer antiretroviral combination regimens in recent years;²
- the addition of PrEP which prevents infection in HIV negative people to the PBS in 2018; and
- the COVID-19 pandemic.

DUSC sought to understand the impacts of these changes on the utilisation of HIV medicines. DUSC requested that the utilisation of antiretroviral medicines for the treatment and prevention of HIV be reviewed using both PBS dispensing data and MedicineInsight data.

This paper reports on the PBS dispensing data analysis.

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.^{4,5} 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 2019.⁴

^a The number of CD4+ white blood cells per cubic millimetre of blood. CD4 cells alert other immune cells to the presence of viral or bacterial threats. A low CD4+ count is an indicator of a weakened immune system.

Most new infections are seen 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.^{4,6}

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 load^b and CD4+ count.⁷

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.⁸ The different classes of medicines include the:⁹⁻¹¹

- nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs); abacavir, emtricitabine, lamivudine, 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:⁹

- bictegravir plus tenofovir alafenamide plus emtricitabine

^b 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 lamivudine^c
- dolutegravir plus (emtricitabine or lamivudine) plus (tenofovir alafenamide or tenofovir disoproxil fumarate)
- dolutegravir plus lamivudine^d
- 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)

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

^d Not recommended for individuals with HIV RNA >500,000 copies/mL, HBV co-infection, or in whom antiretroviral medicines are 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.⁷

Contraindicated antiretroviral regimens and drug-drug interactions with antiretroviral medicine

Australian guidelines note that a number of antiretroviral medicine regimens should not be offered at any time.⁷ A list of these contraindicated regimens and the reasons for this are shown in Table 2.

Table 2: Antiretroviral drug regimens that should not be offered at any time (see the DHHS guidelines for exceptions⁷

Antiretroviral drug regimen	Rationale
Monotherapy with NRTIs	Inferior virological activity plus rapid development of resistance
Dual-NRTI regimens	Inferior virological activity plus rapid development of resistance.
Triple-NRTI regimens	High rate of early virological nonresponse. The only exceptions are abacavir/zidovudine/lamivudine and possibly tenofovir DF + zidovudine/lamivudine (Evidence: BII) in patients in whom other combinations are not desirable
Unboosted saquinavir, darunavir or tipranavir (i.e. not prescribed with cobicistat or ritonavir)	Inadequate bioavailability
Nevirapine + efavirenz, or nevirapine/ efavirenz/ etravirine	Higher incidence of toxicity and similar resistance profiles
Emtricitabine + lamivudine	Similar resistance profiles, no potential benefit
Etravirine + unboosted HIV-PI (i.e. not prescribed with cobicistat or ritonavir)	Etravirine may induce metabolism of HIV-PIs; appropriate doses not yet established
Etravirine + ritonavir-boosted atazanavir or fosamprenavir	etravirine may alter the concentrations of these HIV-PIs; appropriate doses not yet established
Etravirine + ritonavir-boosted tipranavir	etravirine concentration may be significantly reduced by ritonavir - boosted tipranavir

Drug-drug interactions with antiretroviral medicines

A number of non-HIV medicines are contraindicated or to be used with caution in people taking some antiretroviral medicines (Table 3).

Table 3: Drug-drug interactions between specific antiretroviral medicines and medicines for the treatment of conditions other than HIV¹²

Non-antiretroviral medicine	Antiretroviral medicine	Risk	Recommendation
Long term use of corticosteroids*	HIV-PIs or cobicistat	Steroid accumulation, adrenal suppression and Cushing's syndrome	Avoid. If inhaled or intranasal corticosteroids are required, use beclomethasone Avoid use of budesonide, fluticasone and triamcinolone with ritonavir and cobicistat, Avoid use of ritonavir with dexamethasone
Proton pump inhibitors (PPIs)	Rilpivirine or atazanavir	Loss of therapeutic effect of ART	Rilpivirine is contraindicated
Oral contraceptives	HIV-PIs or efavirenz		
Simvastatin	HIV-PIs or elvitegravir + cobicistat + tenofovir + emtricitabine (Stribild) or elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)		

*Corticosteroids include oral, inhaled and intranasal corticosteroids, excluding beclomethasone

Prescribing antiretroviral medicine 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:^{9,11}

- 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.

Information on the prevalence of these conditions among patients prescribed antiretroviral medicines can be found in the companion MedicineInsight report.

Pharmacology

The different classes of antiretroviral medicines target HIV at different stages of the life cycle:¹⁰

- 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.¹⁰

The current Product Informations (PI) and Consumer Medicine Informations (CMI) 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 4 lists 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 4: 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) 10350R (listed July 2015; deleted Dec 2016) 10351T (listed July 2015; deleted Dec 2016) 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)	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) 10325K (listed July 2015; deleted July 2016)
	tenofovir disoproxil (Viread)	J05AF07	10310P (listed July 2015; deleted July 2017) 11142K (listed Aug 2017) 11155D (listed Aug 2017)
	abacavir/lamivudine/zidovudine (Trizivir)	J05AR04	10305J (listed July 2015)

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
	emtricitabine/tenofovir disoproxil (Truvada, Apotex, Cipla)	J05AR03	10347N (listed July 2015; deleted July 2017) 10946D (listed Dec 2016; deleted Apr 2017) 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)
	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	05062K (listed Jan 2012; deleted June 2015) 05084N (listed Jan 2012; deleted June 2015) 10301E (listed July 2015)
	nevirapine (Viramune)	J05AG01	01129K (listed Apr 2012; deleted Mar 2014) 01132N (listed Apr 2012; deleted Mar 2014) 10303G (listed July 2015) 10304H (listed July 2015) 10319D (listed July 2015)
	rilpivirine (Edurant)	J05AG05	01170N (listed Apr 2012; deleted Mar 2014) 01173R (listed Apr 2012; deleted Mar 2014) 10298B (listed July 2015)

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
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	02980W (listed Dec 2013; deleted June 2015) 03392M (listed Mar 2012; deleted June 2015) 05000E (listed Mar 2012; deleted June 2015) 05821J (listed Dec 2011; deleted Nov 2013) 05823L (listed Dec 2011; deleted Nov 2013) 10000H (listed Dec 2013; deleted June 2015) 10287K (listed for July 2015 only) 10329P (listed for July 2015 only) 10367P (listed July 2015)
	darunavir/cobicistat (Prezcobix)	J05AR14	10903W (listed Oct 2016)
	fosamprenavir (Telzir)	J05AE07	10337C (listed July 2015) 10368Q (listed July and Aug 2015 only)
	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 (Telzir, 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	10065R (listed for July 2015 only) 10070B (listed for July 2015 only) 10283F (listed July 2015)
	raltegravir (Isentress)	J05AX08 J05AJ01	02736B (listed Dep 2013; deleted June 2015) 02743J (listed Dep 2013; deleted June 2015) 02754Y (listed Dep 2013; deleted June 2015) 02760G (listed Dep 2013; deleted June 2015) 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 (Eviplera)	J05AR08	01490K (listed June 2012; deleted Mar 2014) 01491L (listed June 2012; deleted Mar 2014) 10314W (listed July 2015; deleted Feb 2020)
	elvitegravir/cobicistat/tenofovir disoproxil/emtricitabine (Stribild)	J05AR09	10085T (listed May 2015; deleted June 2015) 10088Y (listed May 2015; deleted June 2015) 10307L (listed July 2015; deleted Feb 2020)
	abacavir/dolutegravir/lamivudine (Triumeq)	J05AR13	10247H (listed Apr and June 2015 only) 10248J (listed Apr and June 2015 only) 10345L (listed July 2015)

Drug class	Medicine name (Brand name – doesn't include generics)	ATC code	PBS item
	emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey)	J05AR19	11104K (listed May 2017)
	elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya)	J05AR18	10680D (listed April 2016; deleted April 2017) 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)

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

At its November 2013 meeting, the PBAC recommended the removal of the CD4+ requirement from the PBS restrictions for initiation of first-line antiretroviral therapy. The change to the listings was recommended on the basis of acceptable cost-effectiveness over no treatment (deferred therapy).¹

Since this date the PBAC has recommended the listing of the following medicines for the treatment of HIV:

- dolutegravir + abacavir + lamivudine (Triumeq) in November 2014;
- atazanavir + cobicistat (Evotaz) in November 2015;
- tenofovir alafenamide + emtricitabine + elvitegravir + cobicistat (Genvoya) in November 2015;
- darunavir + cobicistat (Prezcobix) in March 2016;
- tenofovir alafenamide + emtricitabine + rilpivirine (Odefsey) in November 2016
- tenofovir alafenamide + emtricitabine (Descovy) in November 2016
- a new 600mg formulation of raltegravir (Isentress) in November 2017
- dolutegravir + rilpivirine (Juluca) in July 2018
- tenofovir alafenamide + emtricitabine + bicitgravir (Biktarvy) in July 2018
- dolutegravir + lamivudine (Dovato) in August 2019. In July 2020, this listing was extended to include the treatment of HIV infection in antiretroviral therapy experienced patients
- darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza) in November 2019.

In December 2017, the PBAC recommended the listing of tenofovir disoproxil + emtricitabine (Truvada and generics) for HIV pre-exposure prophylaxis (PrEP) for adults at medium to high risk of HIV infections. In September 2020, the PBAC recommended amending this listing to allow use in a broader population of at-risk individuals, following the 2019 update to the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines.

In November 2019, the PBAC endorsed authorised nurse practitioner prescribing for HIV medicines under the Highly Specialised Drugs program.

Previous reviews by the DUSC

In 2013, DUSC reviewed the utilisation of antiretroviral medicines for the treatment of HIV.¹³ At this meeting, it noted:

- increasing utilisation of medicines for the treatment of HIV infection was aligned with the increasing population of people living with HIV, increased awareness and diagnosis, lifelong therapy, and government endorsed treatment targets.
- prescribing was in accordance with clinical guidelines.

- consistent with best practice recommendations patients were being started earlier on treatment.

At the time, DUSC noted that the PBS restrictions for most antiretrovirals limited use to patients with a CD4+ count less than 500 cells/mm³ or symptomatic HIV.

For details of the DUSC consideration of HIV medicines, refer to the [Public Release Document](#) from the 2013 DUSC meeting.

Methods

The analyses used 8 years of data from the PBS supplied prescriptions database, managed by Services Australia, for dates of supply from 1 January 2013 up to and including 31 December 2020; extracted August 2021. The PBS supplied prescriptions database includes data submitted to Services Australia for payment of a PBS or Repatriation PBS (RPBS) subsidy by the Government by all approved pharmacies in Australia.

Prescription count analysis

Prescriptions (PBS and RPBS) for antiretroviral medicines dispensed between 1 January 2013 and 31 December 2020 were identified using PBS item codes as per Table 4 for patients included in the study (as per the 'patient count analysis' described below).

Analysis of expenditure

Expenditure was analysed for prescriptions dispensed to patients included in the study (as per the 'patient count analysis' described below). This analysis used information from the PBS supplied prescriptions database on the 'benefit paid by government, less patient co-payment' based on the published listed price. The analysis did not include any changes in the cost of other drugs.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available Services Australia Medicare date of processing data.^e The publicly available Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included. The data used in this report includes under co-payment prescriptions from 1 April 2012.

Patient count analyses

To be eligible for inclusion in the study, patients had to have had at least one PBS or RPBS prescription for an antiretroviral medicine dispensed between 1 January 2013 and 31 December 2020. Only patients aged 18 years or older in each calendar year of interest were included. Patients dispensed tenofovir alone were excluded from the analysis as this was considered to reflect treatment for hepatitis C, not HIV. Patients dispensed tenofovir +

^e PBS statistics. Australian Government Department of Human Services Medicare. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>.

emtricitabine alone, with no record of using any other antiretroviral medicine throughout the study period, were also excluded to avoid the inclusion of patients using this combination for PrEP, not HIV treatment.

Prevalent patients were counted by calendar years from January 2013 to December 2020.

Patients started on an antiretroviral medicine for the first time (incident patients) in a calendar year were defined as patients who did not have a PBS prescription for an antiretroviral medicine supplied in at least the two previous calendar years. As the data supplied was from 1 January 2013, incident patients were counted by calendar year from 1 January 2015 onwards (to provide a minimum of 2 years prescribing history).

Demographic data on patients started on antiretroviral medicines between 1 January 2018 and 31 December 2019 or during calendar year 2020 was also collected to compare with MedicineInsight data and to explore the impact of the COVID-19 pandemic.

Closing the gap (CTG) indicator

This analysis used information from the Closing the Gap (CTG) PBS Co-payment Program. This program is available to Aboriginal and Torres Strait Islander people of any age who are:

- registered with Medicare;
- in the opinion of a prescriber or Aboriginal Health Practitioner would experience setbacks in the prevention or ongoing management of a condition if the person did not take the prescribed medicine; and
- are unlikely to adhere to their medicines regimen without assistance through the program.

PBS prescriptions dispensed under the CTG program were used as a proxy for indigenous status, noting that not all Aboriginal and Torres Strait Islander people will participate in the program and this will underestimate the true rate of dispensing to Aboriginal and Torres Strait Islander people.

Potentially inappropriate medicine use

Drug-drug interactions with antiretroviral medicine combinations

Information on use of antiretroviral regimens that should not be offered to patients as listed in Table 2, was investigated using data from 1 January 2018 and 31 December 2019.

The 'prescription duration' for each dispensed HIV medicine was calculated using the time from the date the first prescription was dispensed to the date the last prescription was dispensed. To avoid the risk that a patient had switched regimens in the period after the last prescription was dispensed (and may not have taken the full course), the duration of the last dispensed prescription was not included.

If the prescription durations of each dispensed antiretroviral medicine overlapped the patient was considered to be using the respective antiretroviral medicines concurrently. A prescription duration was considered to be on-going if there were no gaps between

prescription purchases of greater than 250 days^{f,14}. If there was a gap greater than 250 days between consecutive prescriptions being purchased, the patient was considered to no longer be taking that antiretroviral, and the prescription duration period was determined to have ended on the date of the last prescription purchase before the gap. One continuous duration of antiretrovirals could have multiple regimens, depending on how many overlaps with other antiretrovirals it had.

Drug-drug interactions with non-antiretroviral medicines

Information on use of non-antiretroviral medicines that should be avoided in patients using particular antiretroviral regimens, as listed in Table 3, was investigated using data from 1 January 2018 to 31 December 2019.

A non-HIV medicine was considered to have been co-prescribed with an antiretroviral medicine if the non-HIV medicine was dispensed within 30 days of the date of supply for an antiretroviral medicine. That is any prescription for non-HIV medicines dispensed within the period 30 days before and 30 days after the date of supply of the antiretroviral medicine was considered to be co-prescribing.

Non-antiretroviral medicines were identified via PBS item numbers (see Appendix C).

Statistical analysis

Analyses of the data were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Statistics included frequencies, proportions and measures of central tendency of numeric data as appropriate.

If a particular result was only reported in 1–4 patients, this result has been reported as < 5 (with the exception of missing variables). Complementary suppression of adjacent cells has been applied where necessary to prevent secondary disclosure of small cell numbers.

^f As per the methodology described by Dharan et al¹⁴. Dharan NJ, Radovich T, Che S, et al. HIV treatment regimens and adherence to national guidelines in Australia: an analysis of dispensing data from the Australian pharmaceutical benefits scheme. BMC Public Health 2019;19:13. <https://www.ncbi.nlm.nih.gov/pubmed/30606134> we estimated the cut-off of 250 days using: the average number of days of drug per prescription pack (30 days); the PBS's standard drop-off definition (three times the interval between purchases [26]); and the weighted average number of prescription packs filled per month (2.78): $30 \text{ days} \times 3 \times 2.78 = 250 \text{ days}$.

Results

The selection process and number of patients included in each calendar year is shown in Figure 1 below.

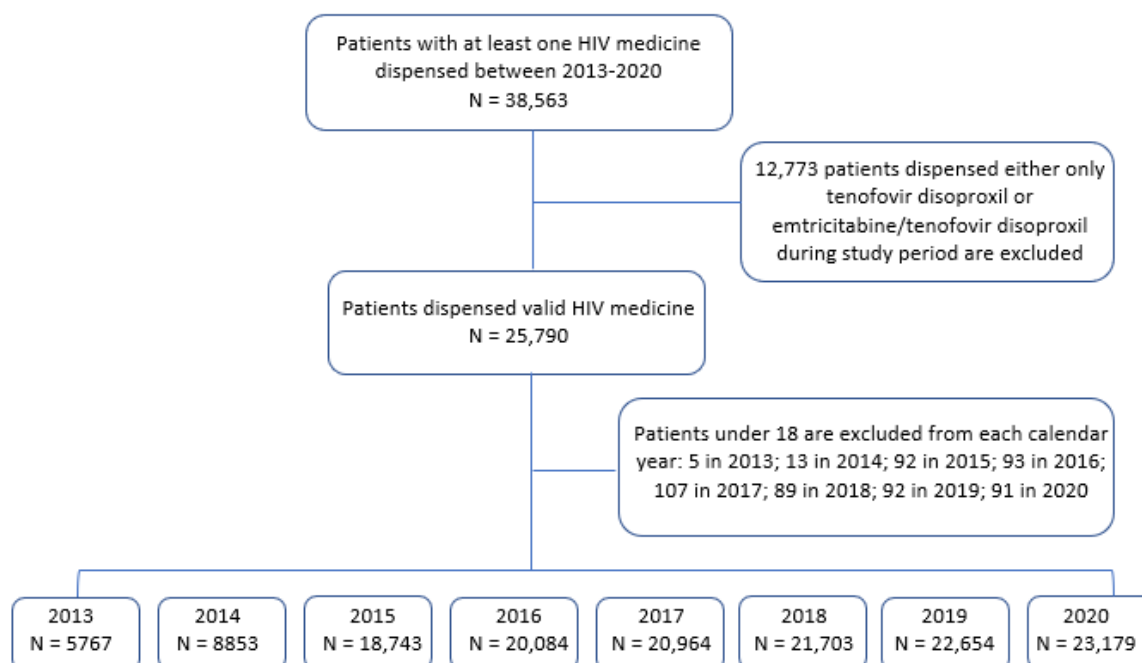


Figure 1: Study flow chart of patients

In 2013 and 2014, there were 5767 and 8853 patients who met our study criteria, respectively. However, according to surveillance data from the Kirby Institute there were 21,360 Australians diagnosed with HIV in 2014 of which 18,156 were using antiretroviral medicines (Appendix E).¹⁵ This suggests that identifying patients using PBS data from 2013 and 2014 is likely to be unreliable.

In July 2015, a change was made to allow patients to access their antiretrovirals from any community pharmacy under the Highly Specialised Drugs (HSD) Community Access program.¹⁶ Prior to this, antiretrovirals could only be dispensed if the patient was receiving care from a hospital, and the prescriber was associated with a hospital. This may have contributed to the rapid jump in patient numbers in 2015 when compared to previous years. Another explanation for the increase in 2015 is the listing of new combination antiretroviral medicines in 2015.

Given the small patient numbers that are inconsistent with HIV surveillance numbers, and the changes to the way antiretroviral medicines were accessed in 2015, all data from 2013 and 2014 should be treated with caution. It has been included for completeness but should not be relied upon. In this report, comparisons between years have been restricted to calendar years from 2015 onwards.

In 2020, there were 23,179 patients who met the study criteria and were dispensed at least one antiretroviral medicine. This is a 24% increase in the number of patients dispensed antiretrovirals since 2015.

Number of prescriptions supplied by class and calendar year

The number of antiretroviral medicines dispensed on the PBS rose rapidly between 2013 and 2016 before stabilising at approximately 130,000 prescriptions per year (Figure 2; Table 4). As previously mentioned this rapid increase is likely to reflect the change to community access arrangements and the listing of new combination antiretroviral medicines in 2015. Prescription numbers prior to 2015 may not be reliable.

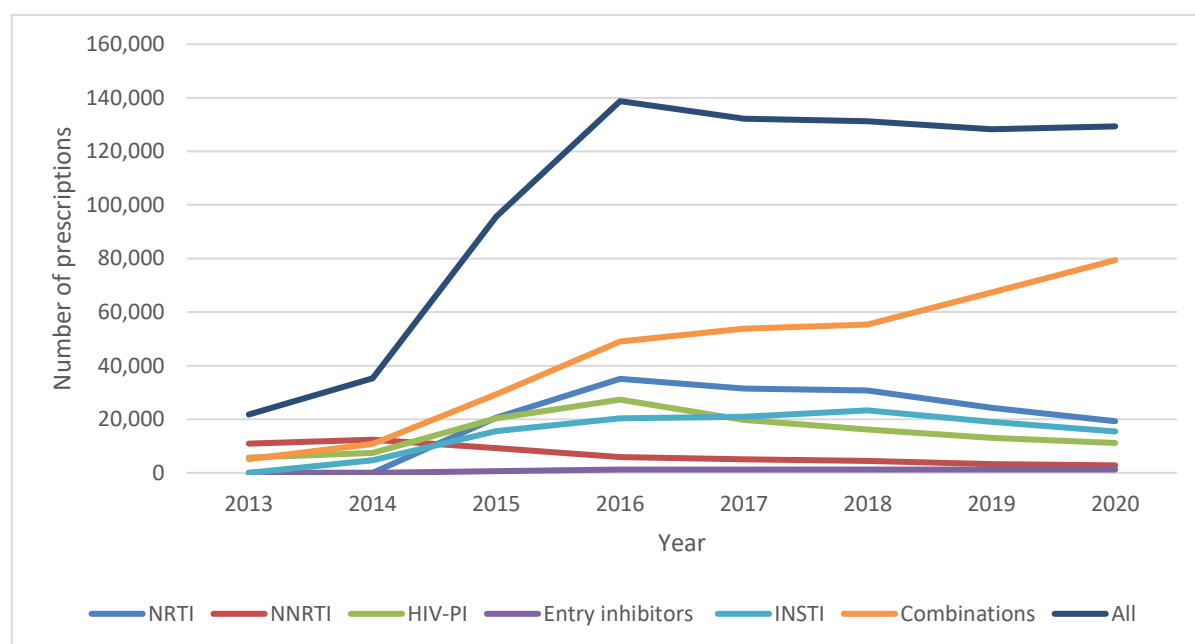


Figure 2: Number of prescriptions dispensed for antiretroviral medicines, by class and calendar year

Note that 2013–2015 data may be unreliable due to the change to community access introduced in 2015

Stabilisation of script numbers from 2017 onwards is likely to reflect a number of factors. These could include fewer new HIV infections and greater awareness of HIV status.⁴ However, it is also likely to be due to the increasing use of combination antiretroviral medicines which replace two or three separate prescriptions with a single prescription (Figure 2).

The combination antiretroviral medicines have become the most commonly dispensed antiretroviral medicines, increasing from 48,981 prescriptions in 2016 to 79,399 in 2020 – a

62% increase (Figure 2; Table 5). Use of this class of medicines continues to increase at the expense of all of the other classes with the exception of entry inhibitors^g.

The total number of dispensed prescriptions for antiretroviral medicines was similar in 2019 and 2020, suggesting that the COVID-19 pandemic had little impact upon supply or access to these medicines. However, large fluctuations in monthly prescription volumes at the beginning of the first wave of the pandemic have been reported for many other medicines used to treat other chronic conditions. Sharp peaks in prescription volumes in March 2020 followed by a steep declines in volumes in April 2020 were reported. This pattern may also have been seen if prescription volumes for antiretroviral medicines had been analysed on a month by month basis.^{17,18}

Table 5: Number of prescriptions supplied for HIV antiretroviral medicines, by class and calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)	2020 No. (%)
NRTI	-	-	20,582 (21.5)	35,079 (25.3)	31,463 (23.8)	30,790 (23.5)	24,315 (19.0)	19,312 (14.9)
NNRTI	10,960 (50.4)	12,365 (35.0)	9261 (9.7)	5841 (4.2)	5080 (3.8)	4398 (3.4)	3265 (2.5)	2797 (2.2)
HIV-PI	5681 (26.1)	7413 (21.0)	20,358 (21.3)	27,327 (19.7)	19,795 (15.0)	16,209 (12.4)	13,110 (10.2)	11,131 (8.6)
Entry inhibitors	-	-	635 (0.7)	1202 (0.9)	1207 (0.9)	1201 (0.9)	1224 (1.0)	1226 (1.0)
INSTI	-	4735 (13.4)	15,566 (16.3)	20,327 (14.7)	20,959 (15.9)	23,314 (17.8)	19,033 (14.8)	15,406 (11.9)
Combinations	5127 (23.6)	10,792 (30.6)	29,264 (30.6)	48,981 (35.3)	53,749 (40.6)	55,357 (42.2)	67,358 (52.5)	79,399 (61.4)
Total	21,768 (100%)	35,305 (100%)	95,666 (100%)	138,757 (100%)	132,253 (100%)	131,269 (100%)	128,305 (100%)	129,271 (100%)

INSTI - integrase strand transfer inhibitors; HIV-PIs - HIV protease inhibitors; NRTIs - nucleoside and nucleotide reverse transcriptase inhibitors; NNRTIs - non-nucleoside reverse transcriptase inhibitors

Number of prescriptions supplied by active ingredient

The listing of bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy) has further increased use of the combination antiretroviral medicines. It is one of the regimens recommended for initial treatment in Australian guidelines.

Listed in March 2019, bictegravir + tenofovir alafenamide + emtricitabine immediately became the most commonly dispensed antiretroviral medicine. There were 20,233 prescriptions dispensed during 2019 (Table 6). This represented 15.8% of all antiretroviral

^g The entry inhibitors are largely reserved from treatment of drug-resistant strains of HIV.7. Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine. HIV Management in Australasia - a guide for clinical care. Sydney: ASHM, 2019. <https://hivmanagement.ashm.org.au/> (accessed 11 August 2021).

prescriptions dispensed that year. In 2020 dispensing of bictegravir + tenofovir alafenamide + emtricitabine increased to 37,681 prescriptions or 29.1% of all antiretroviral prescriptions dispensed during the year.

The next most commonly dispensed medicines in 2020 were:

- abacavir + dolutegravir + lamivudine (Triumeq) with 17,153 prescriptions or 13.3% of all dispensed antiretrovirals. Its use has decreased by 13.2% from a peak of 22,077 dispensed prescriptions in 2018.
- emtricitabine + tenofovir alafenamide (Descovy) with 12,686 prescriptions or 9.8% of all dispensed antiretrovirals. Its use has decreased by 33.5% from a peak of 19,068 dispensed prescriptions in 2018.
- elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya) with 11,421 or 8.8% of all dispensed antiretrovirals. Its use has decreased by 40.9% from a peak of 19,317 dispensed prescriptions in 2018.

Of the above medicines, only elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide is not part of the list of medicines recommended for initiating treatment for HIV.

Table 6: Number of all dispensed prescriptions supplied for HIV antiretroviral medicines, by active ingredient and calendar year

Active ingredient	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)	2020 No. (%)
Nucleoside and nucleotide reverse transcriptase inhibitor (NRTI)								
abacavir (Ziagen)	-	-	787 (0.8)	1356 (1.0)	1160 (0.9)	1046 (0.8)	875 (0.7)	754 (0.6)
lamivudine + zidovudine (Combivir)	-	-	646 (0.7)	1053 (0.8)	748 (0.6)	529 (0.4)	407 (0.3)	342 (0.3)
didanosine (Videx EC)	-	-	69 (0.1)	106 (0.1)	67 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
emtricitabine (Emtriva)	-	-	266 (0.3)	456 (0.3)	378 (0.3)	235 (0.2)	0 (0.0)	0 (0.0)
abacavir + lamivudine (Kivexa)	-	-	4656 (4.9)	6589 (4.7)	4601 (3.5)	3518 (2.7)	2400 (1.9)	1826 (1.4)
lamivudine (Zeffix)	-	-	1304 (1.4)	2361 (1.7)	1915 (1.4)	1746 (1.3)	1761 (1.4)	1572 (1.2)
stavudine (Zerit)	-	-	31 (0.0)	52 (0.0)	23 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)
tenofovir disoproxil (Viread)	-	-	1152 (1.2)	1983 (1.4)	1330 (1.0)	870 (0.7)	607 (0.5)	513 (0.4)
abacavir + lamivudine + zidovudine (Trizivir)	-	-	124 (0.1)	172 (0.1)	133 (0.1)	73 (0.1)	48 (0.0)	24 (0.0)
emtricitabine + tenofovir disoproxil (Truvada, Apotex, Cipla)	-	-	11,443 (12.0)	20,807 (15.0)	11,377 (8.6)	3639 (2.8)	2155 (1.7)	1555 (1.2)
emtricitabine + tenofovir alafenamide (Descovy)	-	-	-	-	9652 (7.3)	19,068 (14.5)	16,020 (12.5)	12,686 (9.8)
zidovudine (Retrovir)	-	-	104 (0.1)	144 (0.1)	79 (0.1)	60 (0.0)	42 (0.0)	40 (0.0)
Non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs)								
efavirenz (Stocrin)	-	-	1051 (1.1)	1588 (1.1)	1250 (0.9)	966 (0.7)	643 (0.5)	492 (0.4)
etravirine (Intelence)	2556 (11.7)	2876 (8.1)	2728 (2.9)	2470 (1.8)	2159 (1.6)	1932 (1.5)	1514 (1.2)	1288 (1.0)

Active ingredient	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)	2020 No. (%)
nevirapine (Viramune)	8131 (37.4)	8936 (25.3)	4678 (4.9)	839 (0.6)	616 (0.5)	424 (0.3)	338 (0.3)	280 (0.2)
rilpivirine (Edurant)	273 (1.3)	553 (1.6)	804 (0.8)	944 (0.7)	1055 (0.8)	1076 (0.8)	770 (0.6)	737 (0.6)
HIV protease inhibitors (HIV-PIs)								
atazanavir (Reyataz)	-	-	3957 (4.1)	5606 (4.0)	3110 (2.4)	2029 (1.5)	1383 (1.1)	1012 (0.8)
darunavir (Prezista)	5681 (26.1)	7413 (21.0)	7632 (8.0)	7510 (5.4)	5497 (4.2)	4622 (3.5)	3765 (2.9)	3180 (2.5)
darunavir + cobistat (Prezcobix)	-	-	-	205 (0.1)	2446 (1.8)	3173 (2.4)	3356 (2.6)	3378 (2.6)
fosamprenavir (Telzir)	-	-	102 (0.1)	142 (0.1)	84 (0.1)	55 (0.0)	48 (0.0)	39 (0.0)
indinavir (Crixivan)	-	-	26 (0.0)	34 (0.0)	19 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
lopinavir + ritonavir (Kaletra)	-	-	1260 (1.3)	1784 (1.3)	1030 (0.8)	646 (0.5)	412 (0.3)	325 (0.3)
ritonavir (Telzir, Norvir)	-	-	7287 (7.6)	11,698 (8.4)	6838 (5.2)	4823 (3.7)	3514 (2.7)	2619 (2.0)
saquinavir (Invirase)	-	-	68 (0.1)	89 (0.1)	65 (0.0)	39 (0.0)	27 (0.0)	17 (0.0)
tipranavir (Aptivus)	-	-	26 (0.0)	35 (0.0)	27 (0.0)	12 (0.0)	12 (0.0)	12 (0.0)
atazanavir +cobicistat (Evotaz)	-	-	-	224 (0.2)	679 (0.5)	807 (0.6)	593 (0.5)	549 (0.4)
Entry inhibitors (Fusion inhibitors and CCR5 inhibitors)								
enfuvirtide (Fuzeon)	-	-	15 (0.0)	19 (0.0)	7 (0.0)	9 (0.0)	10 (0.0)	13 (0.0)
maraviroc (Celsentri)	-	-	620 (0.6)	1183 (0.9)	1200 (0.9)	1192 (0.9)	1214 (0.9)	1213 (0.9)
Integrase inhibitors								
dolutegravir (Tivicay)	-	4724 (13.4)	9612 (10.0)	10,561 (7.6)	13,145 (9.9)	16,518 (12.6)	13,792 (10.7)	11,227 (8.7)
raltegravir (Isentress)	-	11 (0.0)	5954 (6.2)	9766 (7.0)	7814 (5.9)	6796 (5.2)	5241 (4.1)	4179 (3.2)
Combination class antiretroviral medicine								

Active ingredient	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)	2020 No. (%)
efavirenz + emtricitabine + tenofovir disoproxil (Atripla)	-	-	6379 (6.7)	10,457 (7.5)	6752 (5.1)	3989 (3.0)	2394 (1.9)	1414 (1.1)
rilpivirine + emtricitabine + tenofovir (Evipler)	5127 (23.6)	8537 (24.2)	9308 (9.7)	8930 (6.4)	5456 (4.1)	1847 (1.4)	1158 (0.9)	144 (0.1)
elvitegravir + cobicistat + tenofovir disoproxil + emtricitabine (Stribild)	-	2255 (6.4)	5675 (5.9)	4475 (3.2)	1189 (0.9)	598 (0.5)	346 (0.3)	42 (0.0)
abacavir + dolutegravir + lamivudine (Triumeq)	-	-	7902 (8.3)	18,073 (13.0)	20,913 (15.8)	22,077 (16.8)	19,513 (15.2)	17,153 (13.3)
emtricitabine + rilpivirine + tenofovir alafenamide (Odefsey)	-	-	-	-	2972 (2.2)	7480 (5.7)	7285 (5.7)	7686 (5.9)
elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	-	-	-	7046 (5.1)	16,467 (12.5)	19,317 (14.7)	14,903 (11.6)	11,421 (8.8)
bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)	-	-	-	-	-	-	20,233 (15.8)	37,681 (29.1)
dolutegravir + rilpivirine (Juluca)	-	-	-	-	-	49 (0.0)	1501 (1.2)	2331 (1.8)
darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza)	-	-	-	-	-	-	-	460 (0.4)
dolutegravir + lamivudine (Dovato)	-	-	-	-	-	-	25 (0.0)	1067 (0.8)
Total	21,768 (100%)	35,305 (100%)	95,666 (100%)	138,757 (100%)	132,253 (100%)	131,269 (100%)	128,305 (100%)	129,271 (100%)

Expenditure

Government expenditure on antiretroviral medicines in 2020 was \$216.9 million (Figure 3; Table 7). Most of the expenditure on antiretroviral medicines is on combination medicines. In 2020, cost to government for combination medicines was \$157.3 million or 72.5% of total expenditure on all antiretroviral medicines.

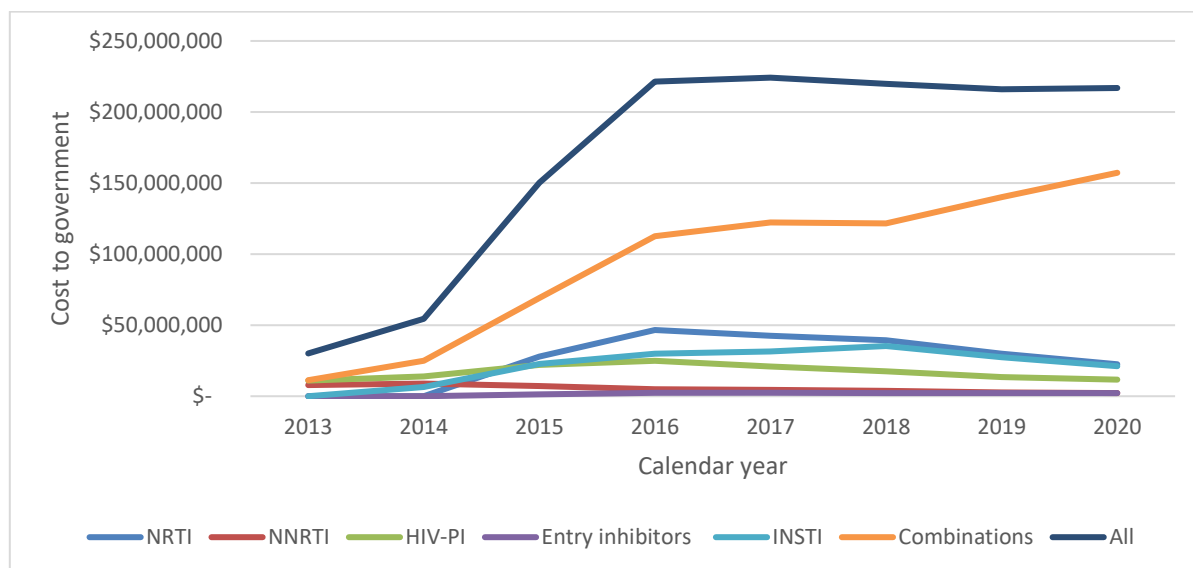


Figure 3: Cost to government for prescriptions supplied for HIV antiretroviral medicines, by class and calendar year.

Note that 2013–2015 data may be unreliable due to the change to community access introduced in 2015

The most expensive individual antiretroviral medicine in 2020 was tenofovir alafenamide + emtricitabine + bictegravir (Biktarvy; \$74.1 million) followed by dolutegravir + abacavir + lamivudine (Triumeq; \$32.5 million).

Table 7: Cost to government (\$) of all supplied prescriptions for HIV antiretroviral medicines, by active ingredient and calendar year

Active ingredient	2013	2014	2015	2016	2017	2018	2019	2020
Nucleoside and nucleotide reverse transcriptase inhibitor (NRTI)								
abacavir (Ziagen)	-	-	479,463	793,143	682,934	559,798	416,351	350,833
lamivudine + zidovudine (Combivir)	-	-	540,248	843,968	505,125	237,412	131,372	69,293
didanosine (Videx EC)	-	-	46,040	67,350	38,118	380	-	-
emtricitabine (Emtriva)	-	-	157,104	260,827	213,589	130,826	-	-
abacavir + lamivudine (Kivexa)	-	-	4,689,082	6,227,066	4,002,084	2,413,292	1,542,350	1,049,258
lamivudine (Zeffix)	-	-	395,804	588,897	358,646	211,952	216,543	198,096
stavudine (Zerit)	-	-	26,510	42,217	18,977	2801	-	-
tenofovir disoproxil (Viread)	-	-	1,287,050	2,133,068	1,311,759	741,921	49,2513	347,419
abacavir + lamivudine + zidovudine (Trizivir)	-	-	187,671	234,026	157,844	70,213	36,466	15,057
emtricitabine + tenofovir disoproxil (Truvada, Apotex, Cipla)	-	-	20,027,565	35,318,614	18,144,885	2,654,261	713,045	334,888
emtricitabine + tenofovir alafenamide (Descovy)	-	-	-	-	17,110,969	32,278,892	26,347,534	20,038,049
zidovudine (Retrovir)	-	-	70,901	95,717	47,984	36,062	22,293	21,750
NRTI Total	-	-	27,907,438	46,604,892	42,592,915	39,337,810	29,918,468	22,424,642
Non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs)								
efavirenz (Stocrin)	-	-	618,348	902,190	701,009	491,972	295,486	223,695
etravirine (Intelence)	3,381,968	3,848,453	3,709,188	3,238,696	2,843,550	2,510,038	1,931,608	1,496,824
nevirapine (Viramune)	4,286,171	4,748,350	2,326,703	316,244	217,235	138,236	70,280	60,583
rilpivirine (Edurant)	139,258	309,356	450,001	562,676	641,126	620,360	428,479	432,649
NNRTI Total	7,807,397	8,906,159	7,104,240	5,019,806	4,402,919	3,760,606	2,725,853	2,213,752

Active ingredient	2013	2014	2015	2016	2017	2018	2019	2020
HIV protease inhibitors (HIV-PIs)								
atazanavir (Reyataz)	-	-	4,992,639	6,834,846	3,872,489	2,377,354	1,258,121	738,327
darunavir (Prezista)	11,007,844	14,006,609	14,343,413	13,472,371	10,028,203	7,972,350	6,149,655	5,151,287
darunavir + cobicistat (Prezcobix)	-	-	-	278,868	3,650,722	4,507,736	4,526,503	4,495,376
fosamprenavir (Telzir)	-	-	90,849	122,122	71,040	41,671	31,355	25,521
indinavir (Crixivan)	-	-	20,647	30,739	16,231	2475	-	-
lopinavir + ritonavir (Kaletra)	-	-	1,835,953	2,572,750	1,510,182	929,982	600,587	458,424
ritonavir (Norvir)	-	-	744,902	1,199,418	753,573	578,679	404,125	309,865
saquinavir (Invirase)	-	-	69,894	91,617	63,150	35,462	23,849	15,696
tipranavir (Aptivus)	-	-	55,665	57,146	42,586	18,302	17,327	17,322
atazanavir + cobicistat (Evotaz)	-	-	-	279,082	910,208	1,003,323	583,599	460,519
HIV-PI Total	11,007,844	14,006,609	22,153,962	24,938,959	20,918,383	17,467,333	13,595,121	11,672,339
Entry inhibitors (Fusion inhibitors and CCR5 inhibitors)								
enfuvirtide (Fuzeon)	-	-	57,174	68,054	20,882	34,891	38,128	47,868
maraviroc (Celenstri)	-	-	1,253,779	2,336,387	2,322,210	2,298,987	2,258,867	2,061,670
Entry Inhibitor Total	-	-	1,310,953	2,404,441	2,343,092	2,333,877	2,296,995	2,109,539
Integrase inhibitors								
dolutegravir (Tivicay)	-	6,547,033	13,823,969	15,664,114	20,122,254	25,494,208	20,659,646	16,050,758
raltegravir (Isentress)	-	20,491	8,821,730	14,203,202	11,442,766	9,838,338	6,897,982	5,167,349
Integrase inhibitor total	-	6,567,524	22,645,698	29,867,315	31,565,019	35,332,546	27,557,627	21,218,107
Combination class antiretroviral medicine								
efavirenz + emtricitabine + tenofovir disoproxil (Atripla)	-	-	15,215,865	23,732,234	14,345,738	7,794,957	3,539,077	906,751

Active ingredient	2013	2014	2015	2016	2017	2018	2019	2020
rilpivirine + emtricitabine + tenofovir (Eviplera)	11,294,055	20,003,508	22,765,656	21,686,647	12,232,291	3,624,739	2,239,784	280,771
elvitegravir + cobicistat + tenofovir disoproxil + emtricitabine (Stribild)	-	4,928,115	13,421,516	10,240,646	2,540,119	1,145,331	670,080	74,564
abacavir + dolutegravir + lamivudine (Triumeq)	-	-	17,804,237	40,678,108	46,950,992	46,268,551	39,741,322	32,462,096
emtricitabine + rilpivirine + tenofovir alafenamide (Odefsey)	-	-	-	-	7,502,809	18,033,150	17,128,532	17,115,801
elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	-	-	-	16,242,945	38,801,668	44,732,904	33,629,111	25,380,052
bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)	-	-	-	-	-	-	40,066,227	74,057,781
dolutegravir + rilpivirine (Juluca)	-	-	-	-	-	98,311	2,941,408	4,374,870
darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza)	-	-	-	-	-	-	-	1,042,869
dolutegravir + lamivudine (Dovato)	-	-	-	-	-	-	37,052	1,560,722
Combination ART Total	11,294,055	24,931,624	69,207,275	112,580,580	122,373,616	121,697,943	139,992,593	157,256,278
Total	30,109,297	54,411,915	150,329,566	221,415,994	224,195,945	219,930,115	216,086,657	216,894,656

Number of unique patients dispensed an antiretroviral medicine

Figure 4 shows the number of unique patients who met the study criteria and were dispensed at least one antiretroviral medicine by calendar year (blue line). The red columns show the number of people living with HIV and using antiretrovirals as reported in the most recent HIV surveillance data published by the Kirby Institute.¹⁵

The number of unique patients who were dispensed at least one antiretroviral medicine has increased slightly year on year since 2015 (Figure 4; Table 8). In 2015, 18,743 patients were dispensed an antiretroviral at least once during the year. In 2020, this had increased by 24% to 23,179 patients.

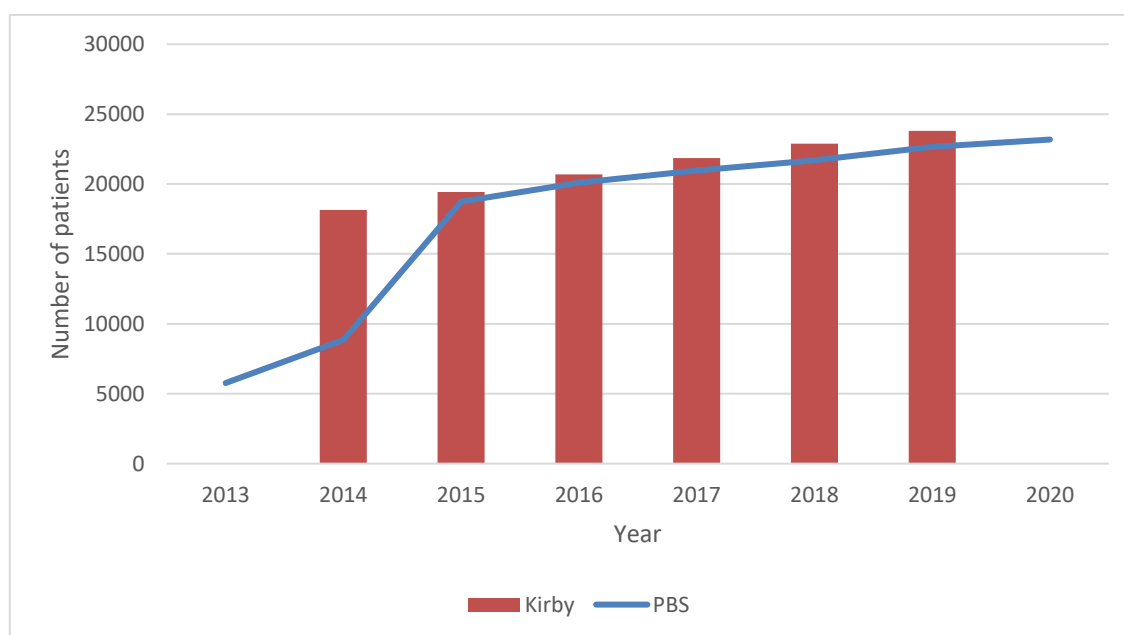


Figure 4: Total number of unique patients dispensed an HIV antiretroviral medicine by year (2013 to 2020), compared with the most recent Kirby Institute HIV surveillance data

Note that 2013–2015 PBS data may be unreliable due to the change to community access introduced in 2015.

The number of patients in 2016 is very similar to that reported in a recent Australian paper.¹⁴ This paper estimated that 19,950 patients were dispensed antiretroviral medicines in 2016 using a 10% national sample of PBS data.

Consistent with other Australia data sources, patients using antiretroviral medicines are most likely to be male (88.3% male in 2020). The life expectancy of PLWHIV has been steadily increasing and almost half are now aged 50 year or older.^{5,19} This trend was also seen in this study. In 2015, 41.8% of patients using antiretrovirals were aged 50 years or older. By 2020, this had increased to 52.7% of all patients using antiretrovirals.

In 2020, 1.1% of patients dispensed an antiretroviral medicine had a CTG indicator, identifying them as being an Aboriginal or Torres Strait Islander. As not all Aboriginal and Torres Strait Islander people participate in the CTG program, this is likely to be an underestimate of the rate of dispensing to these patients. In the companion MedicineInsight study, 2.6–2.8% of patients prescribed an antiretroviral medicine and who

had their Indigenous status recorded, were identified as an Aboriginal or Torres Strait Islander.

Table 8: Annual count of unique patients prevalent to HIV medicines overall , by age, sex and age-sex groups (2013 to 2020)

	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Total	5767	8853	18,743	20,084	20,964	21,703	22,654	23,179
Age* group (10 years)								
18–29	302	623	1213	1288	1296	1320	1293	1193
30–39	872	1548	3337	3588	3732	3749	3926	3958
40–49	2031	2941	5827	5945	5879	5923	5870	5817
50+	2562	3741	8366	9263	10057	10,711	11,565	12,211
Sex**								
Female	467	790	1916	2100	2240	2384	2563	2702
Male	5300	8063	16,827	17,984	18,724	19,319	20,091	20,477
Sex/age group								
Female 18–29	48	94	206	213	203	206	214	198
Female 30–39	139	261	603	623	639	631	645	657
Female 40–49	159	247	593	667	733	808	883	925
Female 50+	121	188	514	597	665	739	821	922
Male 18–29	254	529	1007	1075	1093	1114	1079	995
Male 30–39	733	1287	2734	2965	3093	3118	3281	3301
Male 40–49	1872	2694	5234	5278	5146	5115	4987	4892
Male 50+	2441	3553	7852	8666	9392	9972	10,744	11,289
Closing the gap indicator								
CTG	<5	<5	31	69	114	157	199	257
No CTG	<5767	<8853	18,712	20,015	20,850	21,546	22,455	22,922

*Age was calculated for each calendar year

**47 patients were recorded as being both male and female in a calendar year. The most recent record for sex for each calendar year was used in this analysis.

Note that 2013–2015 data may be unreliable due to the change to community access introduced in 2015.

Number of patients dispensed each class of antiretroviral medicines

Consistent with the increase in the number of prescriptions dispensed, the number of patients who were dispensed a combination antiretroviral medicines has increased (Figure 5; Table 9). In 2015, there were 9707 patients (51.8%) dispensed a combination antiretroviral (. In 2020, this had increased by 94% to 18,859 patients (81.4%).

The most commonly used combination antiretroviral medicine was bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy) which was dispensed to 9119 patients during 2020 (Appendix E; Table E1). The next most commonly dispensed combination antiretroviral medicines in 2020 were abacavir + dolutegravir + lamivudine (Triumeq; 4423 patients) and elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya; 2970 patients).

The next most common class of medicines were the NRTIs which were dispensed to 4843 patients in 2020 (Figure 5; Table 9). The number of patients using these medicines has fallen by 46% since they were first listed in 2015. The most commonly used NRTI was emtricitabine + tenofovir alafenamide (Descovy) which was dispensed to 3292 patients in 2020 (Appendix E; Table E1).

Between 2015 and 2019, there were ~5000–5800 patients dispensed INSTIs each calendar year (Figure 5; Table 9). However, use of the medicines decreased by 30% in 2020 to 3847 patients. This is due to a 30% decrease in the number of patients dispensed single ingredient dolutegravir (Tivicay) as patients were switched to combination antiretrovirals which incorporated an INSTI and other antiretrovirals within the one tablet (Appendix E; Table E1).

The number of patients dispensed NNRTIs and HIV-PIs has been falling since 2015 while the patient numbers for the entry inhibitors have remained steady at approximately 270 patients per year (Figure 5; Table 9).

Note that a patient may have been counted in more than one class of medicines within a calendar year if they switched treatment or were co-administered more than one type of antiretroviral medicine.

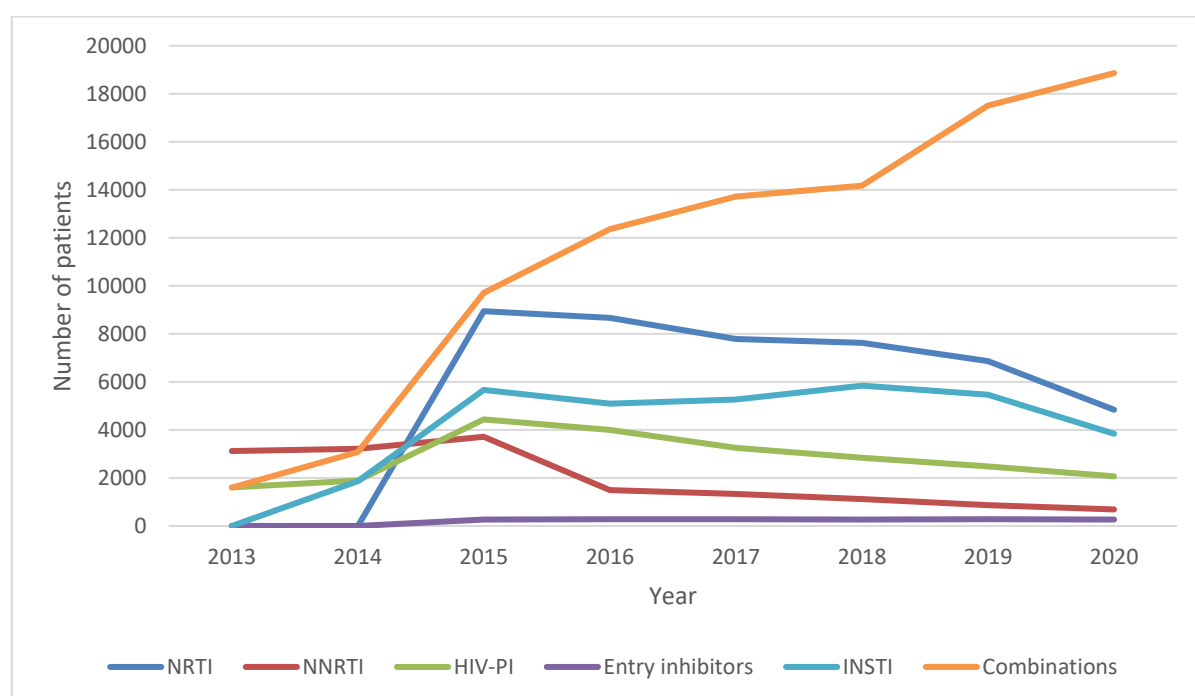


Figure 5: Annual number of patients* using HIV antiretroviral medicines, by class (2013 to 2020)

* A patient may be counted in more than one active ingredient category in a calendar year if they switched treatment or were co administered medicines from more than one class.

Note that 2013 and 2015 data may be unreliable due to the change to community access introduced in 2015

Table 9: Annual count of patients* prevalent to HIV medicines, by class (2013 to 2020)

Class	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
NRTI	-	-	8944	8668	7789	7627	6864	4843
NNRTI	3124	3215	3714	1493	1331	1123	867	688
HIV-PI	1605	1896	4438	3994	3259	2839	2479	2070
Entry inhibitors	-	-	261	275	276	272	282	263
INSTI	-	1861	5668	5089	5266	5845	5473	3847
Combinations	1596	3085	9707	12,356	13,713	14,174	17,512	18,859

* A patient may be counted in more than one active ingredient category in a calendar year if they switched treatment or were co administered medicines from more than one class. Note that 2013–2015 PBS data may be unreliable due to the change to community access introduced in 2015.

Number of patients newly starting HIV antiretroviral medicines

Consistent with national data reporting fewer new HIV infections, greater awareness of HIV status and increasing use of PrEP^{4,20}, and increasing the number of patients started on antiretroviral medicines for the first time has fallen slightly since 2016 (Figure 6; Table 10).

The large number of patients (n = 9995) who appear to have been newly started on antiretrovirals in 2015 is likely to be an artefact of the introduction of community access arrangements in 2015. This data has been excluded from Figures 6 and 7.

Since 2017, the number of patients newly started on antiretrovirals each year has ranged from 1000 to 1343 patients (Figure 6; Table 10). This is higher than the number of new HIV notifications reported each year which typically range between 800–1000 patients per year.^{4,15} Australia has committed to a target of 90% of all people with diagnosed HIV to be on antiretroviral therapy by 2020²¹ and the proportion of patients diagnosed with HIV and prescribed antiretrovirals increased from 87% in 2015 to 92% in 2019.¹⁵ Therefore these higher number of patients newly started on antiretrovirals each may reflect increasing efforts to meet this target. Alternatively it may reflect access by non-Australian citizens under reciprocal care arrangements.

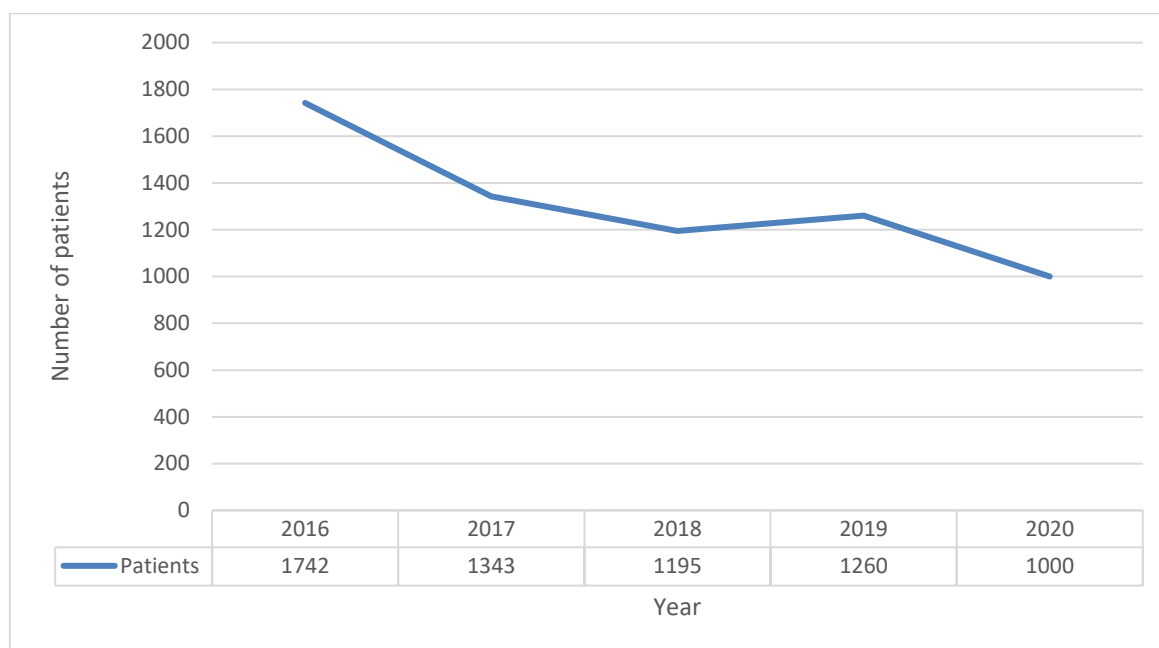


Figure 6: Total number of patients newly started on HIV medicines (2016 to 2020)

Patients who are newly started on an antiretrovirals are most likely to be males aged 30–39 years (Table 10). These patients represented approximately 25% of all patients newly starting antiretrovirals in each year.

Table 10: Annual count of patients* incident to HIV medicines overall , by age, sex and age-sex groups (2015 to 2020)

	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Total	9995	1742	1343	1195	1260	1000
Age group (10 years)						
18–29	700	337	277	283	257	203
30–39	1903	525	408	357	403	313
40–49	3060	466	340	286	282	238
50+	4332	414	318	269	318	246
Sex						
Female	1135	212	189	187	200	163
Male	8860	1530	1154	1008	1060	837
Sex/age group						
Female 18–29	120	48	33	36	46	23
Female 30–39	359	69	74	65	65	56
Female 40–49	352	54	54	53	55	48
Female 50+	304	41	28	33	34	36

	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Male 18–29	580	289	244	247	211	180
Male 30–39	1544	456	334	292	338	257
Male 40–49	2708	412	286	233	227	190
Male 50+	4028	373	290	236	284	210
Closing the gap indicator						
CTG	23	5	16	10	12	7
No CTG	9972	1737	1327	1185	1248	993

*A patient can only be counted once in this analysis

The antiretroviral medicines which patients are most likely to be started on were the combination antiretrovirals (Figure 7; Table 11). In 2016, three quarters of patients were started on a combination antiretroviral but by 2020, 85% of patients newly started on an antiretroviral medicine were started on a combination antiretroviral.

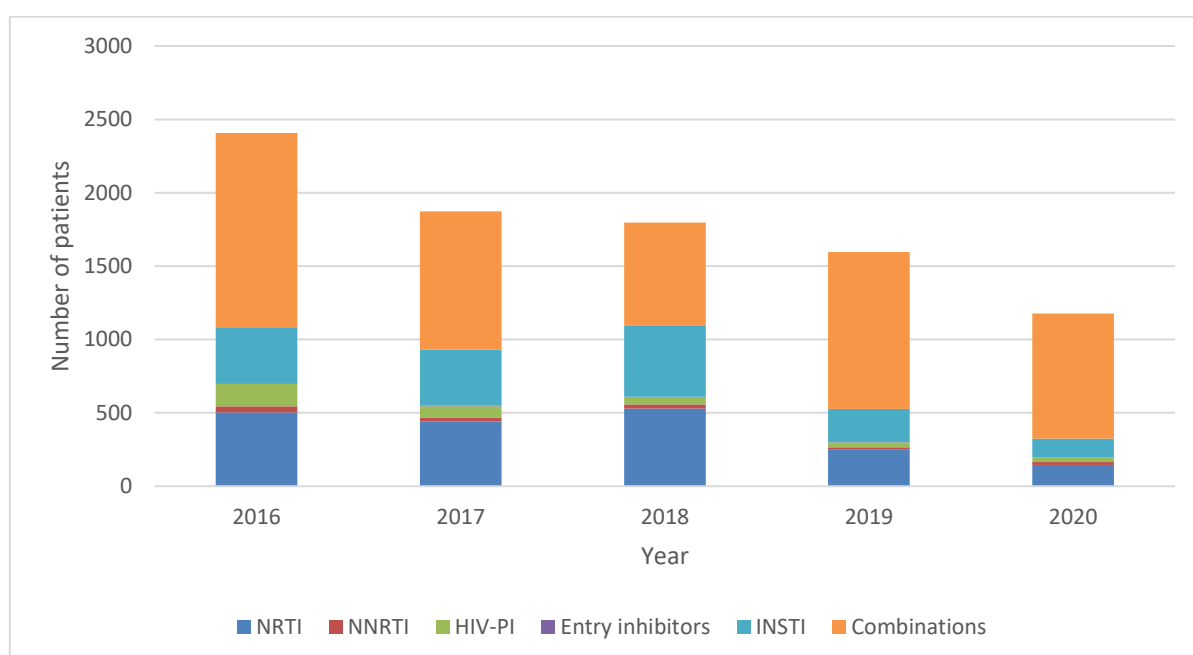


Figure 7: Number of patients* newly started on different classes of HIV medicines (2016 to 2020)

* A patient may be counted in more than one medicine class in a calendar year if they started two medicines in the same calendar year.

Table 11: Annual count of patients* incident to HIV medicines, by class

Class	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
NRTI	503	442	530	252	146
NNRTI	42	24	28	13	19

Class	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
HIV-PI	153	79	47	33	31
Entry inhibitors	0	<5	<5	<5	0
INSTI	381	381	488	227	128
Combinations	1329	944	699	1069	852

* A patient may be counted in more than one medicine class in a calendar year if they started two or more medicines in the same calendar year

In 2017, the combination antiretroviral that the most patients were started on was abacavir + dolutegravir + lamivudine (Triumeq) with 441 patients newly started. In 2020, the combination antiretroviral that the most patients were started on was bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy) with 623 patients newly started.

Demographics of patients dispensed HIV antiretroviral medicines

The demographics of patients in both study periods were similar (Table 12). This suggests that the COVID-19 pandemic did not make it harder for patients from different demographics or geographical locations to access their medicines. However, we may have seen some variations. However, variations may have been seen if the data had been analysed on a quarterly or monthly basis.^{17,18}

Consistent with other Australia data sources, the majority of patients were male and living in major cities. The majority of patients lived in NSW (~38%), Victoria (~27.5%) and Queensland (~18%).

The life expectancy of PLWHIV has been steadily increasing and almost half are now aged 50 year or older.^{5,19} The mean age of patients dispensed at least one antiretroviral medicines on the PBS was 48.6 years (SE 12.6) in study period 1 and 50.1 (SE 12.6) in study period 2.

Approximately 1.0% of patients dispensed an antiretroviral medicine in either study period had a CTG indicator, identifying them as being an Aboriginal or Torres Strait Islander. As not all Aboriginal and Torres Strait Islander people participate in the CTG program, this is likely to be an underestimate of the rate of dispensing to these patients. In the companion MedicineInsight study, 2.6–2.8% of patients prescribed a antiretroviral medicine and who had their Indigenous status recorded, were identified as an Aboriginal or Torres Strait Islander.

Table 12: Demographic characteristics of patients dispensed at least 1 HIV medicine between 1 January 2018 and 31 December 2019 and in 2020

	2018 and 2019 population		2020 population	
	Number	% (95% CI)	Number	% (95% CI)
Total	23,279	100	23,179	100
Sex				

	2018 and 2019 population		2020 population	
	Number	% (95% CI)	Number	% (95% CI)
Male	20,649	88.7	20,477	88.3
Female	2630	11.3	2702	11.7
Age group				
18–29	1616	6.9	1193	5.2
30–39	4235	18.2	3958	17.1
40–49	6298	27.1	5817	25.1
50+	11,130	47.8	12,211	52.7
Sex-age group				
Male 18–29	1355	6.6	995	4.9
Male 30–39	3518	17.0	3301	16.1
Male 40–49	5421	26.3	4892	23.9
Male 50+	10,355	50.2	11,289	55.1
Female 18–29	261	9.9	198	7.3
Female 30–39	717	27.3	657	24.3
Female 40–49	877	33.4	925	34.2
Female 50+	775	29.5	922	34.1
State				
ACT	295	1.3	272	1.2
NSW	8917	38.3	8698	37.5
NT	197	0.9	208	0.9
QLD	4312	18.5	4398	19.0
SA	1067	4.6	1072	4.6
TAS	306	1.3	307	1.3
VIC	6366	27.4	6364	27.5
WA	1819	7.8	1860	8.0
Rurality				
Major city	17,324	74.4	17,394	75.0
Inner regional	3326	14.3	3275	14.1
Outer regional	1716	7.4	1668	7.2
Remote/very remote	381	1.6	394	1.7
Missing	532	2.3	448	1.9
Closing The Gap (CTG) identifier				
CTG	23,043	99.0	22,922	98.9
No CTG	236	1.0	257	1.1

There are differences in patient demographics between this PBS and the companion MedicineInsight report. These are most likely to reflect the distribution of general practices included in MedicineInsight. In brief, the differences were:

- 95% of patients using antiretroviral in MedicineInsight were male compared to 88% in the PBS data;
- 90% of patients in MedicineInsight were from NSW and Victoria compared with approximately 65% in the PBS data;
- more MedicineInsight patients visited metropolitan practices (~87%) compared with the PBS data (~75%).

Patients dispensed potentially inappropriate medicines

There are a number of antiretroviral medicine regimens should not be offered at any time.⁷ Table 13 explores the extent to which such medicines have been dispensed to patient dispensed at least one antiretroviral medicine during 2018 and 2019.

The most commonly identified contraindicated regimen was the use of two NRTIs. There were 1653 patients, or 7.1% of patients dispensed at least one antiretroviral during 2018 and 2019, who were dispensed regimens containing two NRTIs. The other contraindicated antiretroviral regimens were not commonly identified.

Table 13: Number and proportion of patients dispensed at least 1 HIV medicine 1 January 2018 and 31 December 2019 who were dispensed a contraindicated regimen

Contraindicated regimen	2018 and 2019 population (n=23,279)	
	No.	%
Monotherapy with NRTIs	173	0.7
Dual-NRTI regimens	1653	7.1
Triple-NRTI regimens	9	0.0
Unboosted saquinavir, darunavir or tipranavir	122	0.5
Nevirapine + efavirenz, or nevirapine/ efavirenz/ etravirine	0	0
Emtricitabine + lamivudine	410	1.8
Etravirine + unboosted PI	9	0.0
Etravirine + ritonavir-boosted atazanavir or fosamprenavir	11	0.1
Etravirine + ritonavir-boosted tipranavir	0	0

There are a number of non-HIV medicines that should be used with caution or avoided in patients with using particular antiretrovirals.¹² Table 14 explores the extent to which such medicines have been dispensed to the same patient within a month of certain classes of antiretrovirals.

Long term use of corticosteroids may cause problems in people using HIV-PIs or cobicistat.¹² There were 779 patients who had a corticosteroid dispensed within a month of being dispensed a HIV-PI or cobicistat between 1 January 2018 and 31 December 2019.

There were also 304 patients who were dispensed a PPI within a month of being dispensed a regimen containing rilpivirine or atazanavir.

There were very few patients dispensed an oral contraceptive within a month of an HIV-PI or efavirenz dispensing. Similarly, there were very few patients dispensed simvastatin within a month of one of the antiretrovirals listed in Table 14.

Table 14: Patients dispensed a potentially inappropriate medicine combination of a non-HIV medicine and antiretroviral combination between 1 January 2018 and 31 December 2019

Contraindicated regimen	Antiretroviral medicine	No.	%
Corticosteroids (oral and inhaled excluding beclometasone)	HIV-PIs or cobicistat	779	3.3
Proton pump inhibitors (PPIs)	rilpivirine or atazanavir	304	1.3
Oral contraceptives	HIV-PIs or efavirenz	17	0.1
Simvastatin	HIV-PIs or elvitegravir + cobicistat + tenofovir + emtricitabine (Stribild) or elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	11	0.1

Discussion

Since 2016, the number of antiretrovirals dispensed on the PBS has been stable at approximately 130,000 prescriptions per year. Government expenditure has decreased slightly over this time from \$221.4 million in 2016 to \$216.9 million in 2020.

There has been a 24% increase in the number of unique patients being dispensed antiretrovirals each calendar year since 2015. This increase is also seen in HIV surveillance data.¹⁵ While the number of patients has increased, this has had little impact on overall prescription number and costs. This is likely due to the increasing use of combination antiretrovirals which replace two or three separate prescriptions with a single prescription.

The combination antiretrovirals are the most commonly dispensed class and most costly for government. Their use continues to increase thanks to a rapid uptake of bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy) since its listing in March 2019. Biktarvy is one of the regimens recommended for initial treatment in Australian guidelines. In 2020, it was dispensed 37,681 times accounting for 29.1% of all antiretroviral prescriptions that year and \$74.1 million or 34.1% of all government expenditure.

Increasing use of combination antiretrovirals has been at the expense of the other classes of antiretrovirals which has fallen. In 2020, there were:

- 18,859 patients dispensed combination antiretrovirals;
- 4843 patients dispensed NRTIs;
- 3847 patients dispensed INSTIs;
- 2070 patients dispensed HIV-PIs;
- 688 patients dispensed NNRTIs; and
- 263 patients dispensed entry inhibitors.

The number of patients newly started on antiretrovirals has fallen from 1742 patients in 2016 to 1000 patients in 2020. This is consistent with national data reporting fewer new HIV infections each year probably due to greater awareness of HIV status and increasing use of PrEP.^{4,20} Patients newly starting antiretroviral medicines are predominately dispensed combination antiretrovirals. In 2020, 62.3% of patients newly dispensed antiretrovirals were started on bicitgravir + tenofovir alafenamide + emtricitabine (Biktarvy).

There were 1653 patients who were dispensed regimens containing two NRTIs during 2018 and 2019. Australian guidelines note that this regimen should not be offered at any time.

There were small numbers of patients who were dispensed a non-HIV medicine which is contraindicated or to be used with caution in people taking some antiretroviral medicines.

This study found no evidence that dispensing of antiretroviral medicines had been affected by the COVID-19 pandemic during 2020. However, changes in dispensing patterns or the patients dispensed these medicines may have been seen if the data had been analysed on a quarterly or monthly basis.^{17,18}

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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 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.
	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 agent
	rilpivirine	Edurant	Treatment in combination with other antiretroviral medicinal products of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve 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
	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-naïve 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-naïve 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.
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 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	Treatment in combination with other antiretroviral agents for the treatment of HIV-1 infection in antiretroviral experienced patients with treatment failure due to intolerance to previous antiretroviral agents or with evidence of HIV-1 replication despite ongoing therapy.
	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 medicines¹⁰

	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
NNRTIs	zidovudine	Retrovir	Oral, 250–300 mg twice daily
	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.
HIV-PIs	rilpivirine	Edurant	Oral, 25 mg once daily. With rifabutin, oral 50 mg once daily
	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 naive 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
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
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Appendix C: PBS item numbers for non-antiretroviral medicines that should be used with caution

Contraindicated medicine class	Active Ingredient	PBS items
Corticosteroids (oral and inhaled excl. beclometasone)	budesonide	2066R, 2070Y ,2071B ,2072C, 2065Q
	budesonide + eformoterol	2938P, 10015D, 8796Y, 2866W, 8625Y, 10018G, 8750M, 2867X, 10024N
	ciclesonide	8854B, 8853Y
	cortisone	1247P, 1246N
	dexamethasone	2507Y, 1292B
	fludrocortisone acetate	1433K
	fluticasone	8147T, 8345F, 8148W, 8346G, 8516F, 8149X
	fluticasone + eformoterol	10007Q, 10008R, 2827T
	fluticasone + salmeterol	8430Q, 8518H, 8519J, 8431R, 8517G, 8432T
	fluticasone + vilanterol	10199T, 10167D, 11124L, 11129R
	prednisolone	3152X, 1916W, 1917X
	prednisone	1934T, 1936X, 1935W
Simvastatin	simvastatin	2011W, 9242K, 2012X, 9243L, 8173E, 9244M, 2013Y, 9241J, 8313M, 9245N
	simvastatin + sitagliptin	2391W, 2377D, 2383K
Oral Contraceptives	ethinylloestradiol + norethisterone	2776D

	levonorgestrel + ethinyloestradiol	2416E, 1392G, 1456P, 1394J, 1393H
	norethisterone	1967M
	norethisterone with ethinyloestradiol	2775C, 2774B, 2773Y, 2772X
	norethisterone with mestranol	3176E, 3179H
Proton Pump Inhibitors	esomeprazole	10295W, 10343J, 8600P, 8886Q, 10330Q, 10331R, 3401B, 8601Q
	esomeprazole (&) clarithromycin (&) amoxicillin	8738X, 10759G
	lansoprazole	8528W, 8529X, 8949B, 8950C, 9730D, 9731E, 8198L, 9331D, 2240X, 2241Y, 9477T, 9478W
	omeprazole	8332M, 1326T, 1327W, 8331L, 8333N, 9109K, 9110L
	omeprazole (&) clarithromycin (&) amoxicillin	8272J
	pantoprazole	8399C, 9423Y, 9424B, 8007K, 8008L
	rabeprazole	8507R, 8508T, 8509W

Appendix D: Kirby Institute HIV latest surveillance data

HIV diagnosis and care cascade, 2015-2019						
	Year					
	2014	2015	2016	2017	2018	2019
Number of people living with HIV	24,620	25,473	26,480	27,379	28,068	28,918
Number of people living and diagnosed with HIV	21,360	22,241	23,275	24,216	24,973	25,890
Number of people living with HIV and in care	20,336	21,221	22,255	23,205	23,982	24,916
Number of people living with HIV and on ART	18,156	19,421	20,687	21,860	22,876	23,810
Number of people living with HIV with a suppressed viral load	17,042	18,508	19,767	21,221	22,295	23,134
Proportion diagnosed	87%	87%	88%	88%	89%	90%
Proportion in care	95%	95%	96%	96%	96%	96%
Proportion on ART	85%	87%	89%	90%	92%	92%
Proportion suppressed	94%	95%	96%	97%	97%	97%
Prevalence	0.13%	0.13%	0.13%	0.14%	0.14%	0.14%

Source: Kirby Institute HIV latest surveillance data¹⁵ accessed September 2021.

Appendix E: Additional tables

Table E1: Annual count of patients prevalent to HIV medicines, by active ingredient

Active ingredient	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Nucleoside and nucleotide reverse transcriptase inhibitor (NRTI)								
abacavir (Ziagen)	-	-	338	345	293	254	207	162
lamivudine + zidovudine (Combivir)	-	-	282	264	195	145	107	80
didanosine (Videx EC)	-	-	36	27	17	<5	0	0
emtricitabine (Emtriva)	-	-	112	119	92	73	0	0
abacavir + lamivudine (Kivexa)	-	-	2252	1850	1305	965	693	460
lamivudine (Zeffix)	-	-	576	591	505	466	481	432
stavudine (Zerit)	-	-	13	13	7	<5	0	0
tenofovir disoproxil (Viread)	-	-	551	541	402	270	182	147
abacavir + lamivudine + zidovudine (Trizivir)	-	-	57	45	34	20	15	6
emtricitabine + tenofovir disoproxil (Truvada, Apotex, Cipla)	-	-	5303	5465	4577	1146	696	477
emtricitabine + tenofovir alafenamide (Descovy)	-	-	-	-	3759	5082	4823	3292
zidovudine (Retrovir)	-	-	42	41	29	19	17	10
Non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs)								
efavirenz (Stocrin)	-	-	492	417	334	253	171	124
etravirine (Intelence)	684	717	676	602	530	462	377	291

Active ingredient	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
nevirapine (Viramune)	2360	2373	2357	227	175	120	93	66
rilpivirine (Edurant)	90	161	222	263	309	304	237	216
HIV protease inhibitors (HIV-PIs)								
atazanavir (Reyataz)	-	-	1906	1640	915	553	390	247
darunavir (Prezista)	1605	1896	1954	1902	1500	1175	980	782
darunavir + cobicistat (Prezcobix)	-	-	0	162	719	864	925	877
fosamprenavir (Telzir)	-	-	45	35	24	13	10	7
indinavir (Crixivan)	-	-	10	7	5	<5	0	0
lopinavir + ritonavir (Kaletra)	-	-	569	463	285	169	106	77
ritonavir (Norvir)	-	-	3380	3193	1986	1276	949	669
saquinavir (Invirase)	-	-	34	29	18	11	<10	<5
tipranavir (Aptivus)	-	-	10	10	6	<5	<5	<5
atazanavir + cobicistat (Evotaz)	-	-	-	105	213	220	193	151
Entry inhibitors (Fusion inhibitors and CCR5 inhibitors)								
enfuvirtide (Fuzeon)	-	-	7	<5	<5	<5	<5	<5
maraviroc (Clenstri)	-	-	255	<275	<276	<272	<282	<263
Integrase inhibitors								
dolutegravir (Tivicay)	-	<1861	3132	2733	3430	4263	4105	2874
raltegravir (Isentress)	-	<5	2654	2501	2009	1744	1443	1032
Combination class antiretroviral medicine								
efavirenz + emtricitabine +	-	-	2931	2720	1875	1146	737	407

Active ingredient	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
tenofovir disoproxil (Atripla)								
rilpivirine + emtricitabine + tenofovir (Eviplera)	1596	2261	2466	2373	1953	570	350	113
elvitegravir + cobicistat + tenofovir disoproxil + emtricitabine (Stribild)	-	880	1638	1698	377	174	92	36
abacavir + dolutegravir + lamivudine (Triumeq)	-	-	3042	4782	5507	5756	5422	4423
emtricitabine + rilpivirine + tenofovir alafenamide (Odefsey)	-	-	-	-	1463	2083	2088	1979
elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	-	-	-	2865	4527	5072	4556	2970
bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)	-	-	-	-	-	-	6904	9119
dolutegravir + rilpivirine (Juluca)	-	-	-	-	-	49	463	565
darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza)	-	-	-	-	-	-	-	196
dolutegravir + lamivudine (Dovato)	-	-	-	-	-	-	24	408

* A patient may be counted in more than one active ingredient category in a calendar year if they switched treatment or were co administered more than one medicine.

Table E2: Annual count of patients* incident to HIV medicines, by active ingredient (2016 to 2020)

Active ingredient	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Nucleoside and nucleotide reverse transcriptase inhibitor (NRTI)					
abacavir (Ziagen)	11	<5	5	<5	<5
lamivudine + zidovudine (Combivir)	20	5	6	6	6
didanosine (Videx EC)	<5	0	<5	0	0
emtricitabine (Emtriva)	<5	<5	0	0	0
abacavir + lamivudine (Kivexa)	36	24	13	6	12
lamivudine (Zeffix)	18	22	25	26	13
stavudine (Zerit)	<5	0	0	0	0
tenofovir disoproxil (Viread)	28	19	26	22	22
abacavir + lamivudine + zidovudine (Trizivir)	<5	0	0	0	0
emtricitabine + tenofovir disoproxil (Truvada, Apotex, Cipla)	409	172	66	73	51
emtricitabine + tenofovir alafenamide (Descovy)	0	292	421	141	54
zidovudine (Retrovir)	0	<5	<5	0	<5
Non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs)					
efavirenz (Stocrin)	20	8	10	8	7
etravirine (Intelence)	5	6	5	0	0
nevirapine (Viramune)	7	4	5	<5	<5
rilpivirine (Edurant)	10	6	8	3	9
HIV protease inhibitors (HIV-PIs)					
atazanavir (Reyataz)	81	14	10	6	<5
darunavir (Prezista)	52	33	16	8	<5
darunavir + cobicistat (Prezcobix)	9	26	15	17	17
fosamprenavir (Telzir)	0	0	0	0	0
indinavir (Crixivan)	0	0	0	0	0
lopinavir + ritonavir (Kaletra)	16	7	<5	<5	<5
ritonavir (Norvir)	114	34	19	12	6
saquinavir (Invirase)	0	<5	0	0	0
tipranavir (Aptivus)	0	0	0	0	0
atazanavir + cobicistat (Evotaz)	5	<5	<5	0	5
Entry inhibitors (Fusion inhibitors and CCR5 inhibitors)					
enfuvirtide (Fuzeon)	0	0	<5	0	0
maraviroc (Celenstri)	0	<5	<5	<5	0

Active ingredient	2016 No.	2017 No.	2018 No.	2019 No.	2020 No.
Integrase inhibitors					
dolutegravir (Tivicay)	292	322	428	177	91
raltegravir (Isentress)	96	65	69	53	40
Combination class ART					
efavirenz + emtricitabine + tenofovir disoproxil (Atripla)	137	62	48	39	34
rilpivirine + emtricitabine + tenofovir (Eviplera)	75	37	14	11	0
elvitegravir + cobicistat + tenofovir disoproxil + emtricitabine (Stribild)	135	7	5	<5	0
abacavir + dolutegravir + lamivudine (Triumeq)	637	441	300	131	75
emtricitabine + rilpivirine + tenofovir alafenamide (Odefsey)	0	51	70	43	35
elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide (Genvoya)	478	395	290	96	55
bictegravir + tenofovir alafenamide + emtricitabine (Biktarvy)	0	0	0	774	623
dolutegravir + rilpivirine (Juluca)	0	0	3	14	5
darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza)	0	0	0	0	7
dolutegravir + lamivudine (Dovato)	0	0	0	7	56

* A patient may be counted in more than one medicine class in a calendar year if they started two or more medicines in the same calendar year