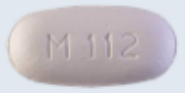

HIV
Treatment
Pipeline

Combination Agents

Tenofovir disoproxil / Emtricitabine / Efavirenz
(tenofovir disoproxil fumerate / emtricitabine / efavirenz)

Biktarvy
(bictegravir / tenofovir alafenamide / emtricitabine)
CURRENTLY NOT PHARMAC FUNDED



Cimduo
(lamivudine / tenofovir disoproxil fumarate)
CURRENTLY NOT PHARMAC FUNDED

Complera
(rilpivirine / tenofovir disoproxil fumarate / emtricitabine)
CURRENTLY NOT PHARMAC FUNDED

Delstrigo
(doravirine / lamivudine / tenofovir disoproxil fumarate)
CURRENTLY NOT PHARMAC FUNDED

Dovato
(dolutegravir / lamivudine)
PHARMAC FUNDED FROM 01/05/24

Genvoya
(elvitegravir / tenofovir alafenamide / emtricitabine / cobicistat)
CURRENTLY NOT PHARMAC FUNDED

Juluca
(dolutegravir/rilpivirine)
CURRENTLY NOT PHARMAC FUNDED

Odefsey
(rilpivirine / emtricitabine / tenofovir alafenamide)
CURRENTLY NOT PHARMAC FUNDED

Stribild
(elvitegravir / cobicistat / emtricitabine / tenofovir)
CURRENTLY NOT PHARMAC FUNDED

Symtuza
(darunavir / cobicistat / emtricitabine / tenofovir alafenamide)
CURRENTLY NOT PHARMAC FUNDED

Symfi Lo
(efavirenz / lamivudine / tenofovir disoproxil fumarate)
CURRENTLY NOT PHARMAC FUNDED

Triumeq
(dolutegravir / abacavir / lamivudine)
CURRENTLY NOT PHARMAC FUNDED

Some people with HIV have difficulty taking treatment every day because of at least the following issues:

- difficulty swallowing pills
- difficulty taking pills every day (and worried about missing a dose)
- difficulty storing pills (particularly if homeless)
- daily pill-taking is an unwelcome reminder of HIV
- inadvertent disclosure if someone sees their medicines

The HIV treatment pipeline is actively exploring new, long-acting antiretroviral therapies (ART) and potential HIV cures, with a focus on reducing the frequency of drug administration. Key areas of development include long-acting injectables, oral therapies with reduced dosing schedules, and novel combinations of existing and new drugs. This research aims to improve patient adherence, convenience, and overall treatment outcomes.

- Key Areas of Innovation:
- **Long-Acting Injectables:**
- Companies are developing long-acting injectables, such as lenacapavir, that can be administered less frequently, potentially every six months, for both treatment and prevention.
- **Reduced Dosing Oral Therapies:**
- Research is focused on developing oral medications with less frequent dosing requirements, including once-weekly and once-monthly options.
- **Novel Drug Combinations:**
- There's a push to combine existing and new drugs, including integrase inhibitors, broadly neutralizing antibodies, and capsid inhibitors, to achieve more effective and durable suppression of the virus.
- **Pro-drugs:**
- Pro-drugs, which are precursors to active drugs, are being explored to improve oral bioavailability and allow for lower doses and smaller pills.
- **Potential Cure Strategies:**
- While a cure is not yet available, research continues to explore strategies like gene editing, broadly neutralizing antibodies, and immunotherapies,

We have a number of potential medicines in development for the treatment and prevention of HIV:

Clinical development pipeline

Compound number / Generic name / Brand name	Indication	Phase	Mode of action / Vaccine type
VH3810109 †	HIV	Phase II	HIV broadly neutralizing antibody
VH3739937	HIV	Phase II	HIV maturation inhibitor
VH4011499	HIV	Phase II	HIV capsid protein inhibitor
VH4524184 †	HIV	Phase II	HIV integrase inhibitor
GSK1265744 cabotegravir	HIV	Phase I	HIV integrase inhibitor

†In-license or other alliance relationship with third party

- Examples of Drugs in Development:

- **Lenacapavir:** A long-acting injectable which inhibits the HIV-1 capsid is being developed by Gilead Sciences for both treatment (Monthly) and prevention (6 Monthly).

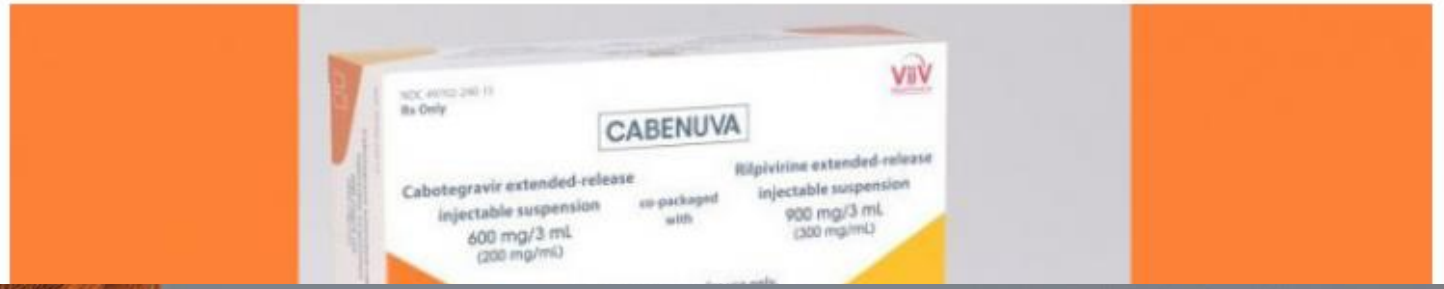
- **Islatravir:** An investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI) being studied in combination with lenacapavir.

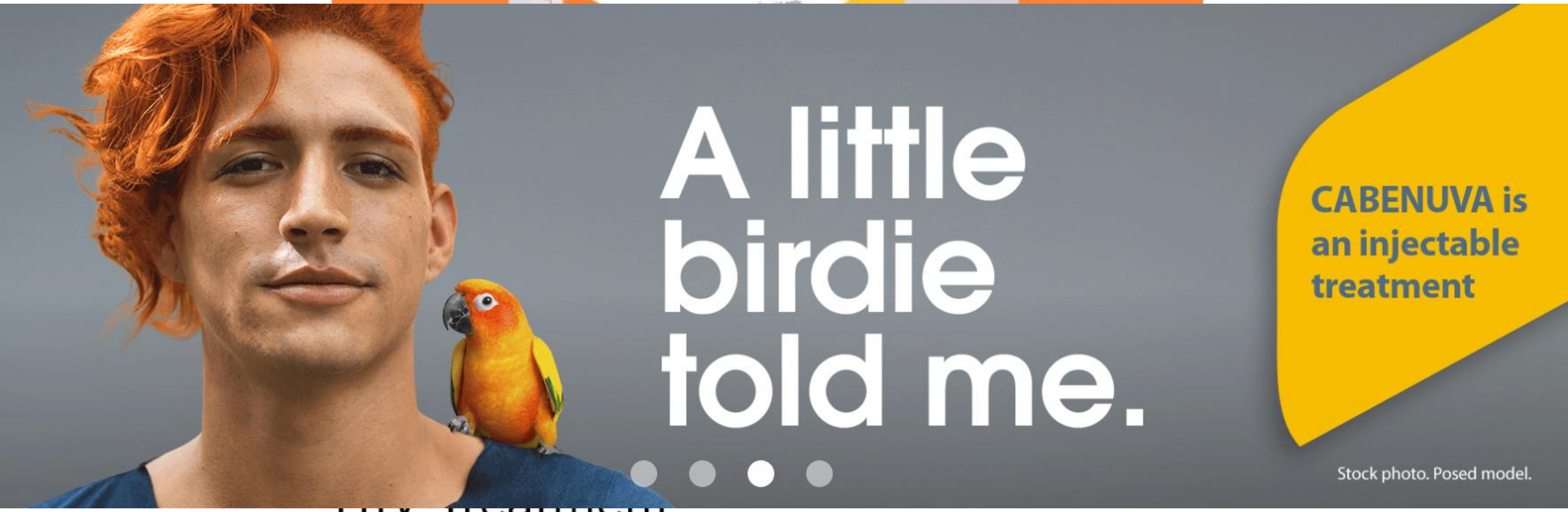
- **GS-1720:** A once-weekly integrase inhibitor being studied by Gilead.

- **GS-4182:** A lenacapavir pro-drug being studied by Gilead.

- **GS-1219 and GS-3242:** Long-acting injectable integrase inhibitors being explored by Gilead as potential partners for lenacapavir.

- MK 8527 – a once monthly oral NNRTTI for prevention by MSD



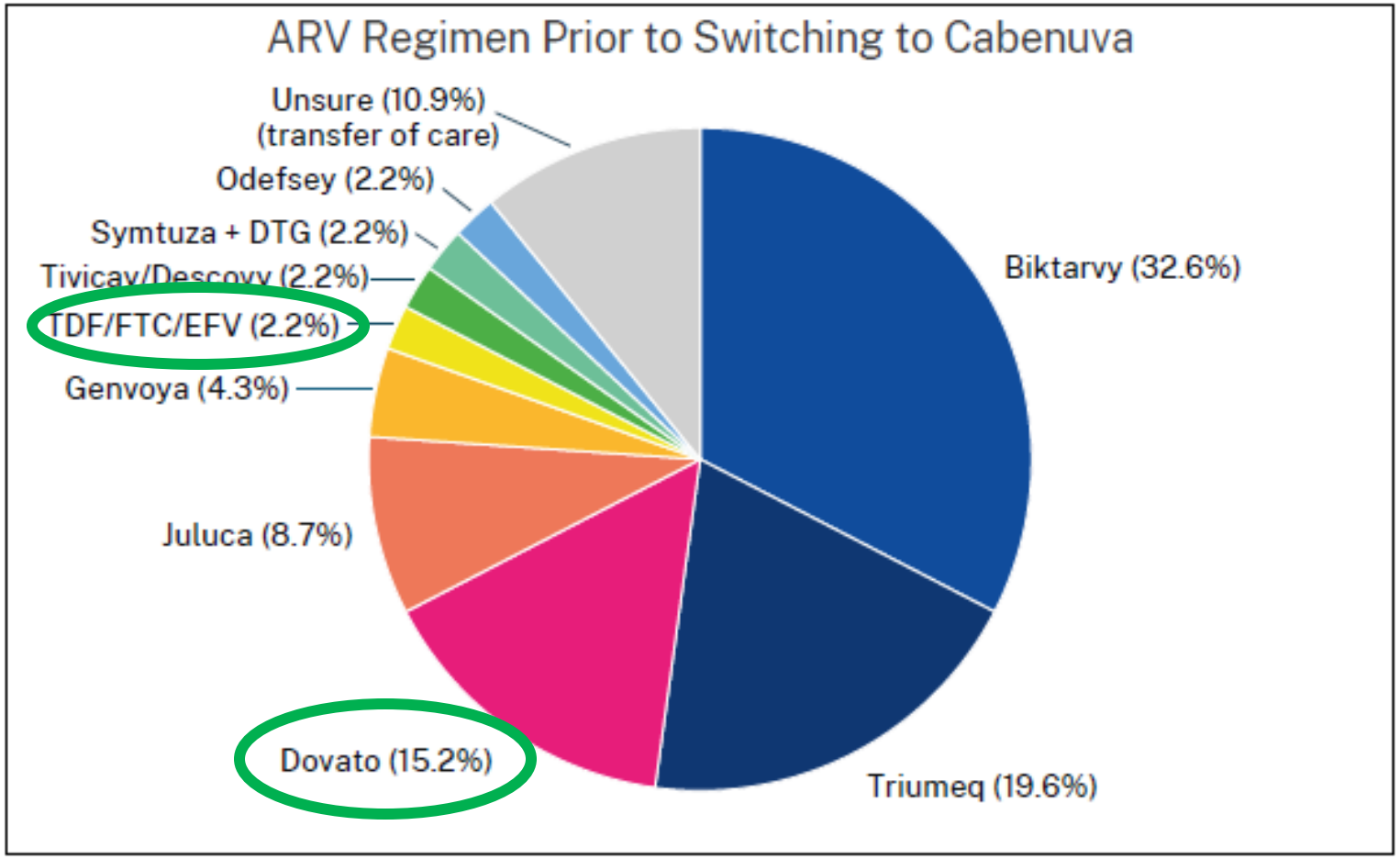


January 21, 2021 By Liz Highleyman (/author/liz-highleyman)

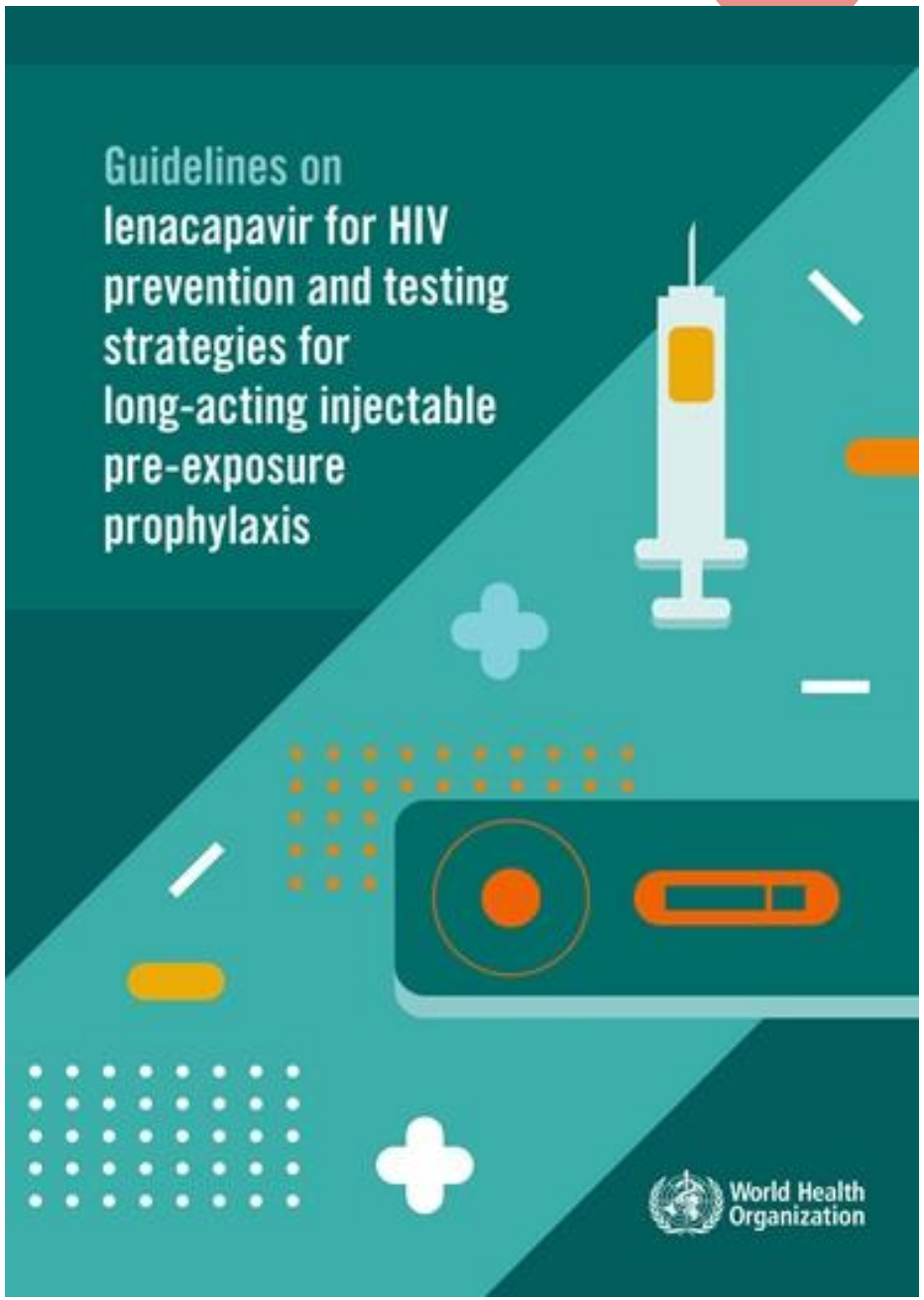
Long Acting Cabotegravir/Rilpivirine Uptake, Adherence and Discontinuation in a High Case Load Publicly Funded Sexual Health Service in Central Sydney, New South Wales.

Bowden B[1], Lim Y[1,2], Acklom, K[1].

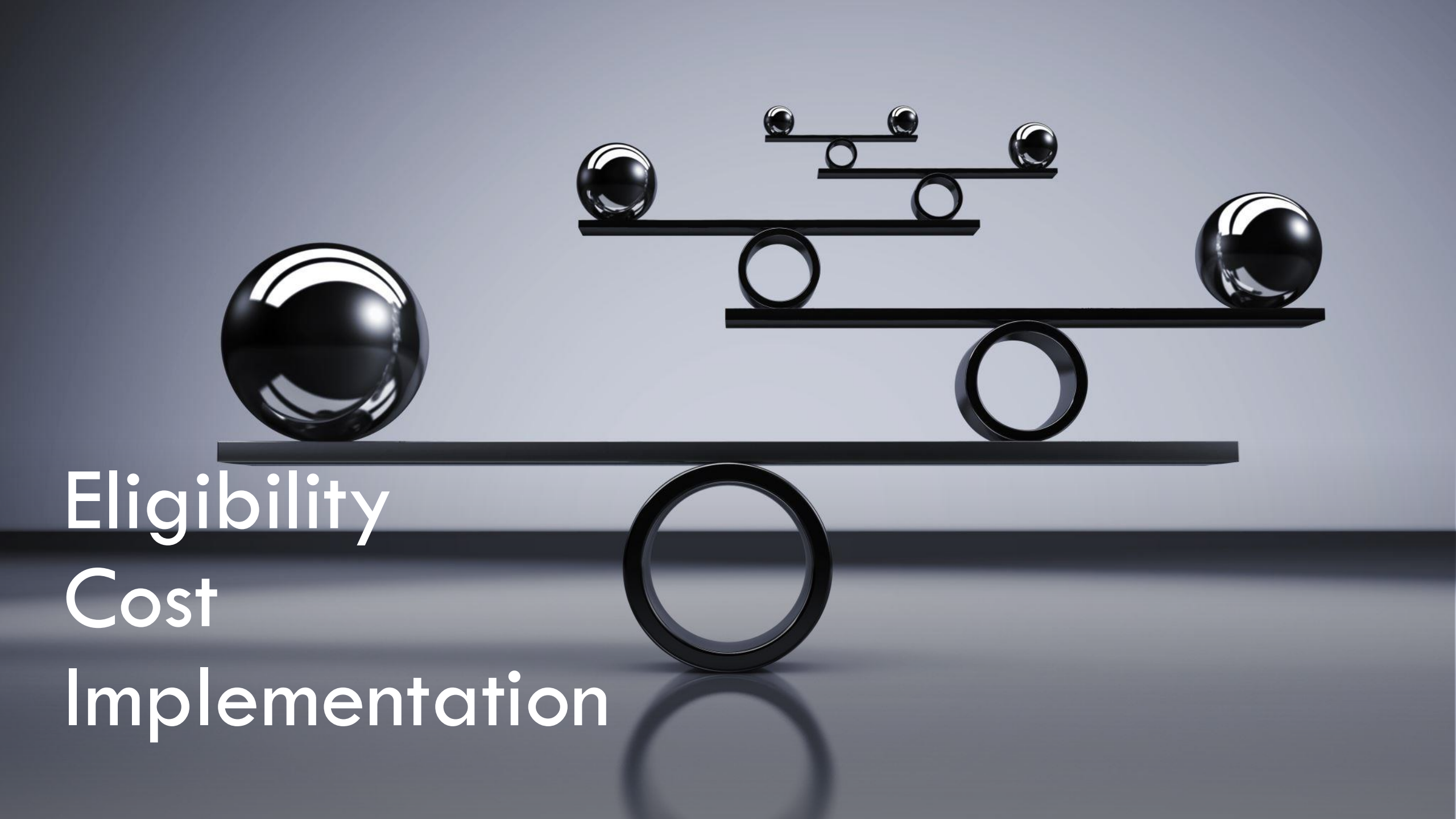
[1] The Albion Center, South-Eastern Sydney Local Health District, Sydney, NSW Australia [2] Port Kembla Sexual Health Service, Illawarra Shoalhaven Local Health, Wollongong, NSW, Australia



Clients who commenced/received Cabenuva from 1 June 2022 to 31 March 2024 were included in this retrospective audit to assess Cabenuva uptake, adherence and discontinuation



Long-acting injectable cabotegravir + rilpivirine can be used as an alternative switching option for adults and adolescents with undetectable HIV viral load on oral ART and without active hepatitis B infection.(Conditional recommendation, moderate-certainty evidence)


Eligibility
Cost
Implementation

Long-Acting Injectable HIV Treatment Tool

ashm

Only one long-acting (LA) injectable treatment option is TGA-approved in Australia: long-acting cabotegravir + rilpivirine (CAB + RPV LA).

CAB + RPV LA can only be prescribed by HIV s100 prescribers. It must be the sole PBS-subsidised prescribed therapy for a patient living with HIV.

POTENTIAL BENEFITS

LA injectable HIV treatment can be beneficial for patients who:

- have disclosure concerns related to storing or taking oral HIV medication.
- experience pill fatigue or burden.
- have a job or lifestyle that impedes oral medication adherence (e.g. frequent travellers, shift workers).
- do not want to be reminded about their HIV status on a daily basis.
- want to avoid taking medication orally.

Overall treatment satisfaction remains very high with <5% of patients switching back to oral therapy. [1]

IS YOUR PATIENT SUITABLE?

- ✔ They are an adult.
- ✔ They have previously received PBS-subsidised therapy for HIV.
- ✔ They are virologically suppressed: HIV-1 RNA <50 copies/mL.
- ✔ They do NOT have known or suspected treatment resistance to CAB or RPV.

  Note: *Some NNRTI resistance mutations (e.g. K103N) will not affect RPV susceptibility. Expert advice may be valuable, see also NNRTI Resistance Notes - HIV Drug Resistance Database*
- ✔ They have NO contraindicated drug interactions (note that intramuscular RPV can be used with PPI therapy)
  - **Anticonvulsants:** phenytoin, phenobarbital, carbamazepine and oxcarbazepine
  - **Antimycobacterials:** rifabutin, rifampicin, rifapentine
  - **Glucocorticoids:** systemic dexamethasone (except as a single dose treatment)
  - **St John's-wort** (Hypericum perforatum)
- ✔ They do NOT have chronic hepatitis B.
- ✔ They are NOT currently pregnant or breast/chestfeeding.

  Note: *There are no studies of CAB+RPV LA in pregnant people. This treatment is listed under the B1 category and, therefore, should only be used during pregnancy if the expected benefit justifies the potential risk to the fetus*
- ✔ They can incorporate ongoing 2-monthly clinic visits into their life and understand the implications of missed or delayed injections.

DISCUSS WITH YOUR PATIENT

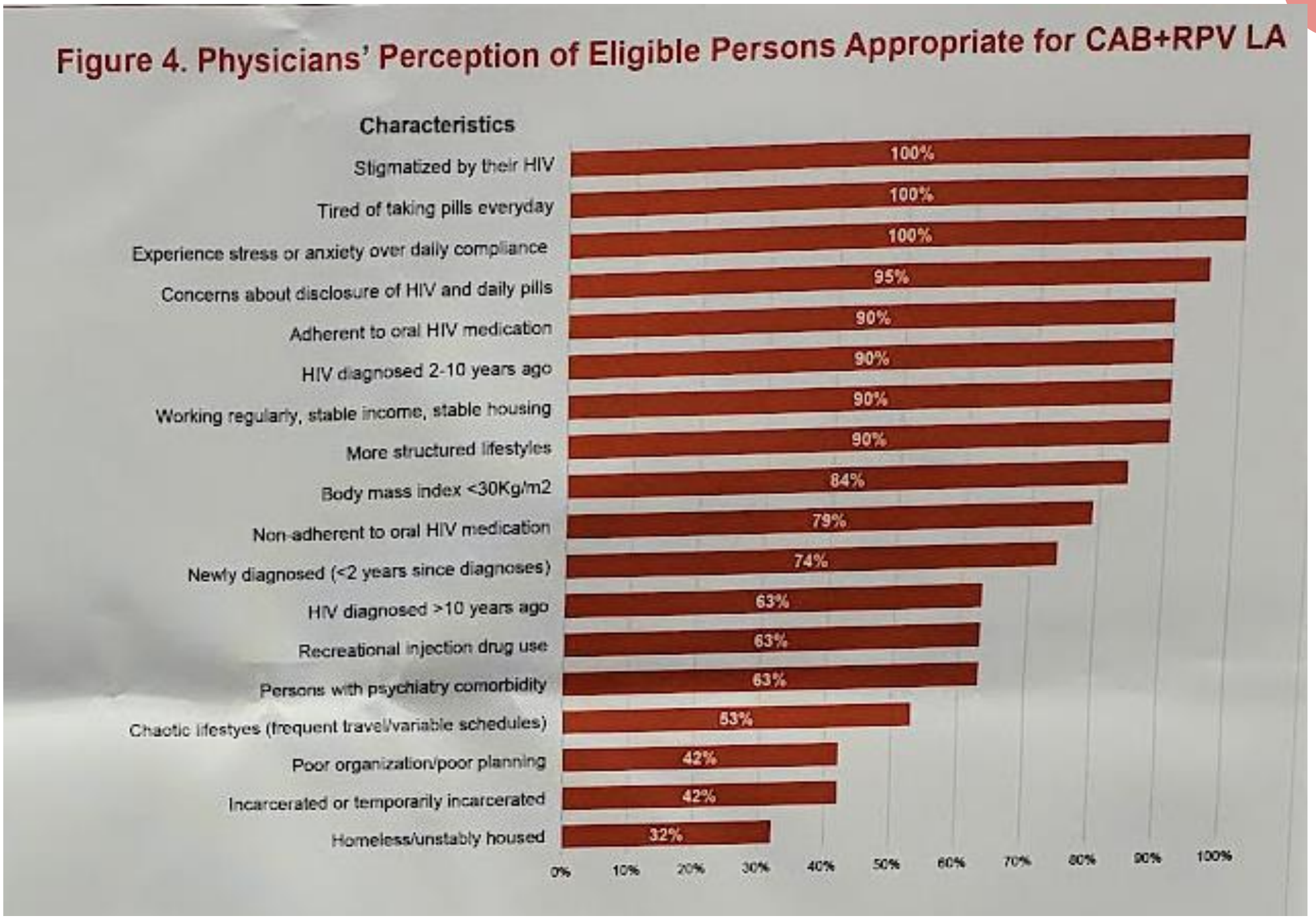
- Potential injection site reactions and side effects
- The injection schedule
- Missed injection protocol

See next page for more information >

GLOSSARY:

TGA: *Therapeutic Goods Administration* **PBS:** *Pharmaceutical Benefits Scheme* **NNRTI:** Non-nucleoside reverse transcriptase inhibitor **PPI:** Proton-pump inhibitor **INSTI:** Integrase strand transfer inhibitor **NSAID:** Non-steroidal anti-inflammatory drugs

Figure 4. Physicians' Perception of Eligible Persons Appropriate for CAB+RPV LA



Australian Government
Department of Health, Disability and Ageing

PBS The Pharmaceutical Benefits Scheme

Enter a medicine, drug, brand name or item number | PBS MEDICINE SEARCH

PBS Information | Browse the PBS | For Health Professionals | For Industry | News | Publications & Downloads | Contacts

CABOTEGRAVIR (&) RILPIVIRINE

Source: S100 HSD Community Access

Body System: ANTIINFECTIVES FOR SYSTEMIC USE > ANTIVIRALS FOR SYSTEMIC USE > DIRECT ACTING ANTIVIRALS

Note

Authority Required (STREAMLINED)

Code & Prescriber	Medicinal Product Pack (Name, form & strength and pack size)	Max qty packs	Max qty units	No. of repeats	DPMQ	Max Safety Net	General Patient Charge
12937X (MP) (NP)	CABOTEGRAVIR (&) RILPIVIRINE cabotegravir 600 mg/3 mL modified release injection [3 mL vial] (&) rilpivirine 900 mg/3 mL modified release injection [3 mL vial], 1 pack (PI, CMI) **Available brands** Cabenuva	1	1	5	$2828.88	$31.60	$31.60

PHARMAC
TE PĀTAKA WHAIORANGA

Section B - Therapeutic Groups > **Search: dovato**

Community Schedule

Rules and glossary | PSO List | Extemp

Strand Transfer Inhibitors

Dolutegravir with lamivudine

- Special Authority SA2139 [PDF] -- Retail pharmacy

Tab 50 mg with lamivudine 300 mg

Brand	Pharmacode	Subsidy	Measure / Qty
✓ Dovato	2674335	$1090.00	per 30

For Media and Investors only

ViiV HEALTHCARE EXTENDS VOLUNTARY LICENSING AGREEMENT WITH MEDICINES PATENT POOL TO ENABLE ACCESS TO INNOVATIVE LONG-ACTING INJECTABLE HIV TREATMENT

- *Agreement allows manufacturers to develop, manufacture and supply generic long-acting injectable cabotegravir (CAB LA) for treatment in 133 countries*
- *Builds on the voluntary licence for CAB LA for HIV pre-exposure prophylaxis (PrEP), enabling increased access to innovative long-acting injectables for HIV treatment*

This includes all least-developed, low-income, lower middle-income and Sub-Saharan African countries, as well as countries where ViiV does not have patent rights for cabotegravir.

THE INJECTION SCHEDULE [2,3]

Initiation → **Continuation**

Month 1

Month 2

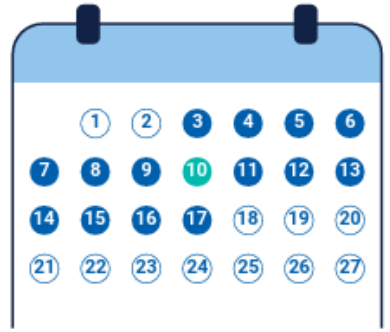
Months 4, 6 and beyond

The first two injections are administered one month apart.

Oral lead-in therapy is not required, but it can be considered in cases where an assessment of tolerance is desired.

For the duration of treatment, ongoing injections are administered every two months.

- It's important that clinicians and patients set a **consistent target injection date.** Opting for the same date or day each month can enhance patient recall. E.g. Every 10th or every second Thursday of the month.
- There is a 'window period' allowing for injections to be given up to 7 days before or 7 days after the target injection date.
- If the patient receives their injection within this window period, the next injection should still be scheduled for the original target injection date.



Target injection date
Window period

MISSED INJECTIONS

(after initation injections)

Planning missed injection/s (e.g. long overseas trip)	**≤2 months break:** Commence oral CAB & RPV on the next target injection date
	>2 months break: Commence alternative oral HIV treatment on the next target injection date
Unplanned missed injection/s	**≤3 months since last injection:** Resume injections as soon as possible and continue with the 2-monthly injection schedule.
	>3 months since last injection: Repeat initiation injections as soon as possible (1 month apart for 2 consecutive months) before resuming the 2-monthly injection schedule.
After an unplanned missed injection, the clinician and patient should jointly reassess if this treatment remains suitable.	

POSSIBLE SIDE EFFECTS

- The most frequently reported side effects for this treatment are injection site pain/a hardened lump (76%), headache (7%), and pyrexia (7%). [2,4]
- Less common side effects are outlined in the Consumer Medicine Information summary. [5]
- Injection site pain can be reduced by starting paracetamol or NSAID therapy the day before the injection and continuing as needed for 2-3 days afterwards.
- Cold packs can also be used, although this is not routine.
- Patients should avoid strenuous gluteal exercises for 12-24 hours after an injection.

PREPARE YOUR PRACTICE

Ensure your practice or clinic is prepared to offer this treatment, considering:

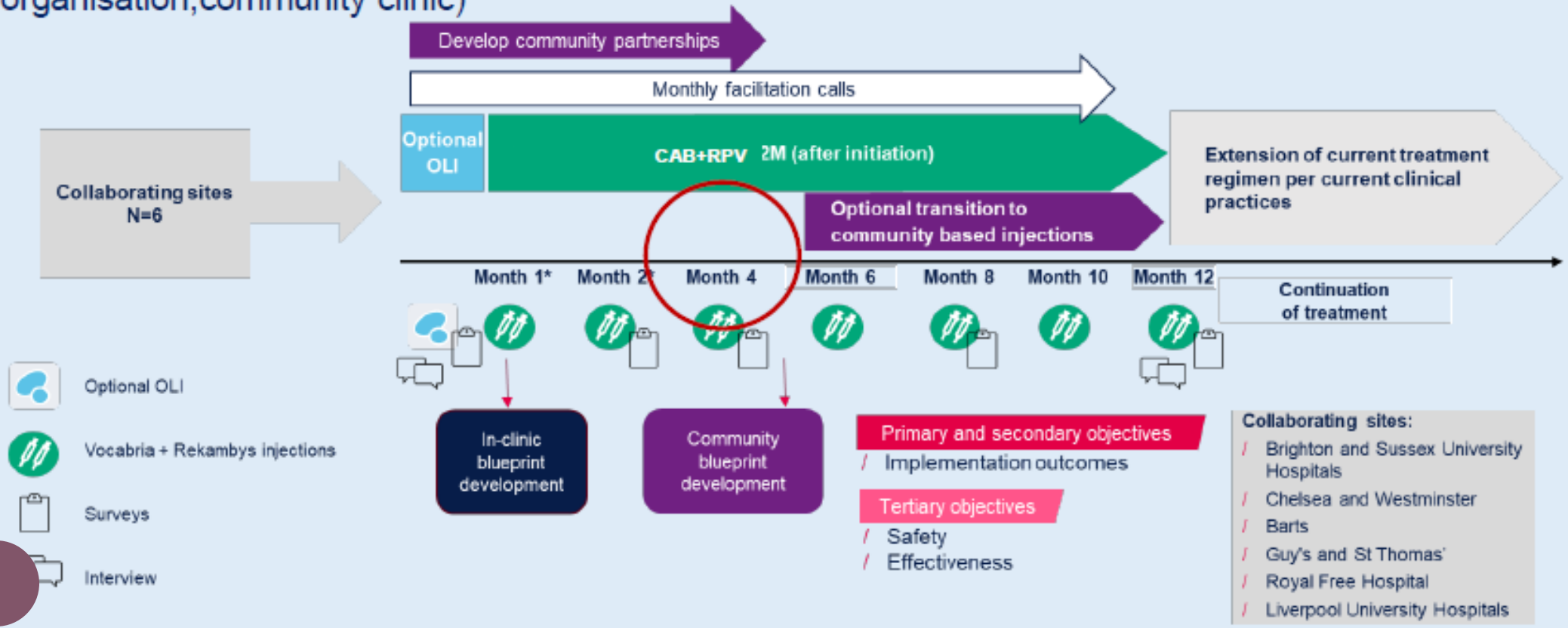
- staff training, awareness and protocols.
- the supply process for treatment availability.
- an efficient patient booking and recall system.

REFERENCES:

1. Ramgopal MN, et al. Efficacy, safety, and tolerability of switching to long-acting cabotegravir plus rilpivirine versus continuing fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with HIV, 12-month results (SOLAR): a randomised, open-label, phase 3b, non-inferiority trial. Lancet HIV 2023 Sep;10(9):e566-e577.
2. Australian Government Therapeutics Goods Administration. PDF. Australian Product Information CABENUVA cabotegravir prolonged-release suspension for injection and rilpivirine prolonged-release suspension for injection [cited 11 March 2024]. Available from: https://www.tga.gov.au/resources/artg/323784
3. ViiV Healthcare. CABENUVA Dosing & Administration. https://cabenuvahcp.com/dosing-and-administration/dosing/#dosing-guide. Published January 2024. Accessed 11 March 2024.
4. Overton ET, et al. Long-Acting Cabotegravir and Rilpivirine Dosed Every 2 Months in Adults With Human Immunodeficiency Virus 1 Type 1 Infection: 152-Week Results From ATLAS-2M, a Randomized, Open-Label, Phase 3b, Noninferiority Study. Clin Infect Dis. 2023 May 3;76(9):1646-1654.
5. Australian Government Therapeutics Goods Administration. PDF. CABENUVA Consumer Medicine Information (CMI) summary. [cited 14 March 2024]. Available from: https://www.tga.gov.au/resources/artg/323784

Methods

- ILANA is a 1-year implementation science study,
- Participants with viral suppression switched to 2-monthly injectable CAB+RPV
- M1-6 was delivered in clinic with an option to continue M6-12 in the clinic or community (eg home, community organisation,community clinic)



Sponsor: Queen Mary University of London (ViiV supported)
Equitably implementing Cabotegravir and Rilpivirine implementation through an anti-racist, anti-sexist, anti-ageist study design

*Initiation Dose 1 was received at Month 1, Initiation Dose 2 at Month 2, with the remaining doses Q2M thereafter
ILANA https://clinicaltrials.gov/ct2/show/NCT05294159 (Accessed Mar 2024)

Results – Preferences/concerns

- At M4, 95% preferred injectables over oral medication

- Top 4 concerns with oral regimen at baselime:
  - having to hide medication from others (43%)
  - daily reminder of HIV status (38%)
  - problems remembering to take pills (20%)
  - inconvenience (13%)

- Top 3 reasons for preferring injection at M4 :
  - convenience (72%)
  - reduced worries about remembering pills (67%)
  - not having to carry medication (67%)

Hikina

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

3 APRIL 2025

Rule of Two for faster access to medicines

HON DAVID SEYMOUR

Health

Associate Health Minister David Seymour is welcoming Cabinet's decision to enable medicines to be approved in less than 30 days if the product has approval from two recognised overseas jurisdictions.

GILEAD

MSD