# **Long-Acting Injectable HIV Treatment Tool**



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.
  </p>
- ✓ They do NOT have known or suspected treatment resistance to CAB or RPV.

Note: Some NNRTI resistance mutations (e.q. 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

# THE INJECTION SCHEDULE [2,3]

#### Continuation Initiation









Months 4, 6 and beyond

one month apart.

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

The first two injections are administered

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
- 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

