CLINICAL GUIDELINE

Long-Acting Injectable Cabotegravir-PrEP

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Lead Author:	Kay McAllister
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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Clinical Pathway for Long-Acting Injectable Cabotegravir-PrEP

Cabotegravir for HIV pre-exposure prophylaxis (CAB-PrEP) is now included in the NHSGGC formulary. Due to the high drug-cost, eligibility criteria for those who may be suitable for CAB-PrEP is still to be agreed locally and nationally but is likely to include:

- Those for whom oral tablets are not an option
- Those who may benefit from, but have issues with consumption of, oral PrEP e.g. tablets cannot be hidden from partner or family but adherence to treatment regimen is assured
- Those with significant renal dysfunction (both oral PrEP options not suitable)

Initiation

The following pathway is proposed for those initiating CAB-PrEP:

1. Any clinician who identifies a patient with a possible need for CAB-PrEP discusses initially with GUM-DoD. If GUM-DoD agrees CAB-PrEP may be appropriate then the patient should be booked directly into a PrEP Medically Complex appointment. If an urgent/early appointment is required then the GUM-DoD should discuss the patient at the next local MDT and follow up arranged in PrEP Medically Complex thereafter (or GUM complex appointment if there is no capacity in PrEP Medically Complex clinics within 2 weeks).
2. Following assessment at PrEP Medically Complex, if deemed appropriate for CAB-PrEP, they are brought to local MDT for approval.
3. Ordering of CAB-PrEP stock will be tightly managed with regular review to ensure stock available for all patients started on it.

Clinical pathway for Initiating those on CAB-PrEP:

1. Brought to next available PrEP Medically Complex appointment (or Socially Complex appointment if this is more appropriate)
2. Counselling completed and consent form signed (see appendix 1)
3. Baseline testing to include:
    1. 4th generation HIV Ag/Ab test and HIV VL
    2. Syphilis serology, HBcAb and HCV PCR
    3. Pregnancy test if applicable
    4. NAAT testing for CT/GC (throat, rectal, urine/VVS as appropriate)
    5. LFTs
    6. Discuss and document contraception encouraging LARC if required +/- cervical screening if appropriate.
4. If HIV Ag/Ab test and HIV VL tests are negative then administer CAB-PrEP as per Option A or B below, according to clinician assessment and patient preference

Side effects

All patients should be counselled about possible side effects including:

- Injection site reactions
- Headache
- GI upset
- Possibility for weight gain (especially if switching from TDF-PrEP)

Contraindications to CAB-PrEP:

- People living with HIV
- People with severe allergic reactions or anaphylaxis to Cabotegravir
- Anyone on the following drugs (which significantly reduce cabotegravir plasma concentrations to subtherapeutic levels):
    - Anticonvulsants: carbamazepine, oxcarbazepine, phenytoin or phenobarbital
    - Anti-mycobacterial agents: rifampicin, rifabutin and rifapentine
- Cabotegravir is not known to be safe in pregnancy or during breastfeeding and therefore should only be used if the benefit clearly outweighs the risk and after wider-MDT discussion

Monitoring

Window period testing:

1. Arrange HIV Ag/Ab and HIV VL testing 45 days after last UPAI/UPVI

8 weekly monitoring (at time of each CAB-PrEP injection):

1. HIV ab/ag and HIV VL testing
2. Pregnancy testing if applicable
3. Assess for symptoms of acute HIV at every visit.

3-6 monthly monitoring (this could align with alternative CAB-PrEP injections i.e. every 16 weeks):

1. NAAT testing for CT/GC (throat, rectal, urine/VVS as appropriate)
2. Syphilis serology
3. LFTs

Annual monitoring:

1. HBcAb
2. HCV PCR (more regular in those at higher risk – see Hepatitis CEG)

Administration

Option A: Direct to injection:

- Administer Cabotegravir 600 mg IM gluteal injection
- Schedule next injection in 4 weeks' time
- Continue injections 8 weekly thereafter

Option B: Oral lead-in phase

- Daily oral cabotegravir 30 mg for 4 weeks
- Schedule first injection 4 weeks after starting oral cabotegravir
- Schedule next injection 4 weeks after first injection
- Continue injections 8 weekly thereafter

Time to Protection against HIV

Cabotegravir is effective as HIV-PrEP 1 week after the first injection. During this time patients should be advised to use condoms.

We do not have adequate data to determine if oral cabotegravir is effective as HIV-PrEP. Therefore if patients commence the oral cabotegravir lead-in, they should be advised to use condoms during these 4 weeks and for 1 week after the first injection.

Follow Up

Follow up should be in Medically or Socially Complex PrEP clinics (whichever is most clinically appropriate for the patient) every 8 weeks. The next appointment should be booked at the time of each injection.

In the rare event that there is no capacity in the Complex PrEP clinics then these patients can be booked into GUM Complex appointments.

Planned missed injections

Individuals should aim to receive their injection on the same date every 8 weeks. If needed, injections can be given up to 7 days before or after the next planned injection. It will be at the discretion of the clinician whether to give 4 weeks of oral Cabotegravir to have "in reserve" which can be used in the event of a missed injection.

- Daily oral cabotegravir can be taken for up to 2 months
- The first dose of oral cabotegravir should be taken 2 months (+/- 7 days) after the last injection
- Injections should be resumed on the final day of oral cabotegravir, or within 3 days thereafter

Missed injection visit	Time since last injections	Recommendation
Injection visit 2	≤ 2 months	**Resume continuation injections** Administer APRETUDE injection as soon as possible and continue with every-2-month injection schedule
	> 2 months	**Restart initiation injections** Administer 1 APRETUDE injection a month for the next 2 consecutive months, then follow every-2-month injection schedule
Injection visit 3 or later	≤ 3 months	**Resume continuation injections** Administer APRETUDE injection as soon as possible and continue with every-2-month injection schedule
	> 3 months	**Restart initiation injections** Administer 1 APRETUDE injection a month for the next 2 consecutive months, then follow every-2-month injection schedule

Table 1: guidelines for missed injection (ViiV)

Unplanned missed injection pathway:

- If an individual misses their appointment, they should be contacted by telephone by the clinician responsible for the clinic, and booked into a Medically or Socially Complex PrEP clinic within the next 7 days.
- If they are not contactable by telephone, they should be texted with the medical secretaries number and advised to contact as soon as possible within 7 days.
- The medical secretaries can then book them directly into a Medically or Socially Complex PrEP clinic within 7 days of their missed appointment.
- At the time of the missed appointment they should also be added to the following week's Medically Complex Clinic (if available) and further attempts to contact them at this appointment (if no success in the interim) and to advise them to commence oral Cabotegravir.

- At their next appointment the patient should be reminded of the importance of on-time injections and their suitability for CAB-PrEP re-assessed.
- At any stage in the above pathway, if a Medically or Socially Complex PrEP appointment is not available within 7 days then they can be booked into GUM Complex or UCC after discussion with GUM DoD.

Stopping CAB-PrEP

Those wishing to stop CAB-PrEP should be offered an alternative method of HIV prevention according clinical scenario and patient acceptability for 12 months. They will remain under follow up in Medically/Socially Complex PrEP clinics to ensure 3 monthly HIV ab/ag and VL testing is completed.

Appendix 1: Consent Form for Those Commencing CAB-PrEP

The following form can be used at the discretion of the senior GUM clinician assessing the patient. It may support shared-decision making and re-enforce the importance of good adherence.

Cabotegravir Injectable PrEP Consent Form

You have been assessed as eligible for injectable cabotegravir PrEP. Cabotegravir is likely to be >99% effective at preventing HIV when taken exactly as prescribed*. This requires you to get your first injection at your first appointment, then a second injection at an appointment 4 weeks later. You will then have injectable cabotegravir at appointments every 8 weeks after that.

It is **very important** that you attend **every appointment** for injectable cabotegravir PrEP. If you know you are going to miss an injection then cabotegravir tablets may be provided for you to take **every day** instead. These tablets will cover you from the **day of your missed injection** for up to **30 days**. You will then need to have an injection within that 30-day period. Injections must then resume every 8 weeks.

Attending is **very important** because cabotegravir injection stays in the body for a long time. As the levels of injected cabotegravir go down after 8 weeks, it will **no longer provide protection from getting HIV**. If you then get HIV after not attending your appointments , the leftover cabotegravir in your system means that the HIV in your body may **become resistant** to some types of treatment. This type of HIV resistance is especially important to avoid because it **reduces the treatment options** available for HIV.

If you wish to stop taking the injections you **must tell us as soon as possible**. If you stop attending appointments for the injections, we will contact you to arrange appropriate follow-up. Not attending your appointments or stopping the injections will result in needing another form of HIV-PrEP for up to **12 months after your last injection** to stay protected, and you will continue to be seen in our PrEP clinc.

Cabotegravir PrEP will only be administered if you are able to agree to the following statements:

By accepting Cabotegravir PrEP I agree to:

☐ Attend scheduled appointments and reschedule appointments if I cannot attend

☐ Tell Sandyford staff as early as possible when I know I will miss an appointment

☐ Take oral cabotegravir once daily for up to 30 days after a missed injection if required

☐ Tell Sandyford staff when I want to stop taking Cabotegravir PrEP

☐ Use alternatives to Cabotegravir PrEP if required for up to 12 months from last injection

☐ Inform sexual health services when I move (understanding that Cabotegravir PrEP could potentially not be provided in the country/area that I move to)

☐ Tell Sandyford Staff if any of my medical history changes

☐ Tell Sandyford Staff if any of any of the previously agreed upon statement change

Signed: Date:

*there are no clinical trials that directly compare those taking Cabotegravir PrEP and those who do not take any PrEP