

CABOTEGRAVIR[®] LONG-ACTING FOR PRE-EXPOSURE PROPHYLAXIS (PREP)

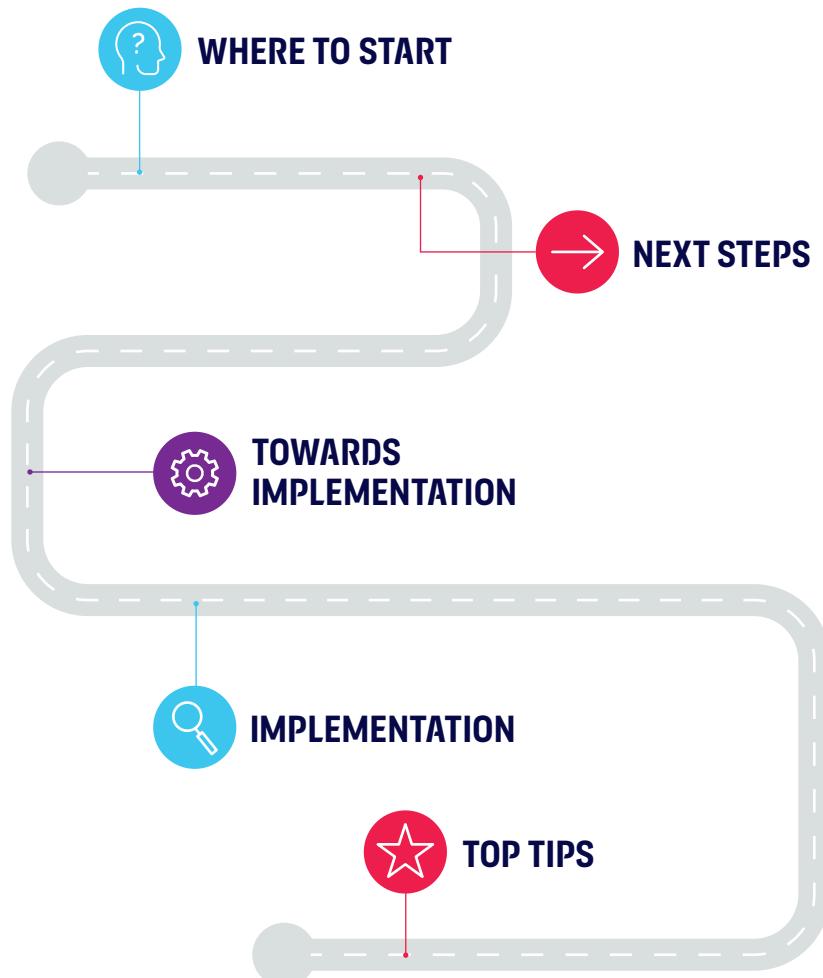
Implementation Guide





WHERE TO START

Sexual health is innovative and as specialists in the field, we respond to developments and scientific data to evolve our services.





INTRO

The aim of this guidance is to support Healthcare Professionals (HCPs)* in the implementation of long-acting Injectables (LAIs) into their clinical setting. Apretude ▼ (cabotegravir) is a long-acting injectable PrEP, indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 acquisition in high-risk adults and adolescents, weighing at least 35 kg.¹ This implementation guide is intended to build confidence, capacity and resource within the clinical setting. Throughout this guide, you will find useful information, including resources and templates to assist with the process of implementation.



Things to consider:

- **Who will be involved** in incorporating and delivering LAIs into the service?
- Develop a **working group**. Think about who needs to be involved. HCPs who are key to running the service, e.g. patient representation, nurses, doctors, pharmacists, health advisors, admin staff, operations and clinical leads.
- Consider your **clinical environment and space**. What are the practical implementation requirements in your sexual health clinic or outreach service?
- Consider **networking**, such as liaising with other centres that are currently using cabotegravir for PrEP and online resources to support your knowledge and skills
- When preparing to begin, **start with small steps to build confidence**. This approach may vary depending on your clinical setting. Consider easing into the process by gradually scheduling and staggering patients' initial appointments

*HCPs – may include doctors, nurses, pharmacists and health advisors



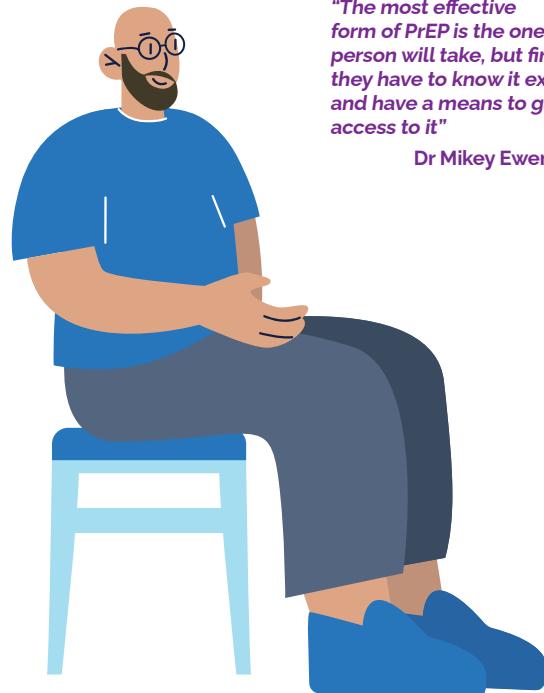
NEXT STEPS

Things to consider:

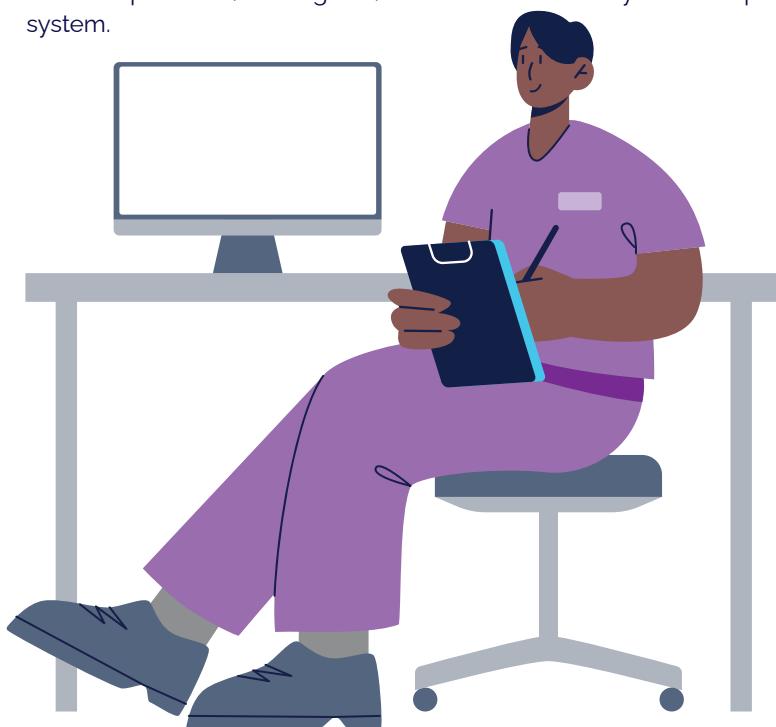
- Practicalities and logistics: Consider day(s) of the week to deliver cabotegravir for PrEP clinics, and whether standalone injectable clinics are required versus absorbing injection appointments into existing clinics
- If clinic space is limited consider alternative sites for delivery, for example women's health hubs, primary care or community hubs, social enterprise spaces & outreach settings
- Cabotegravir for PrEP does not require refrigeration. Do not freeze the vial. Do not store above 25°C
- Follow local guidance on the safe transport of medications

"The most effective form of PrEP is the one a person will take, but first they have to know it exists and have a means to gain access to it"

Dr Mikey Ewens



- Staffing levels: Consider skill mix of the team; for example, utilising different staff grades and other disciplines to task shift and administer injections
- Competencies of staff: Ensure appropriate training has been carried out and utilise experts outside of the clinic for best practice sharing
- Ensure equity of access across the clinic and that resources available are tailored to cohort demographics, informing patients of their HIV prevention options including cabotegravir for PrEP
- Ensure access to the Medicines Procurement and Supply Chain (MPSC) framework and be a Purchasing Point (in England) to ensure continuity of medicines supply (see QR code for BASHH Toolkit).
- Enable access to Blueteq system to ensure reimbursement (in England).
- Ensure Apretude (cabotegravir) is on local formulary or local prescribing system.





TOWARDS IMPLEMENTATION

Education:

- Educating all clinical and non-clinical staff on the patient journey
 - Dosing schedule^{1,2}
 - Cancellations and rescheduling appointments so injections are given within 7 days before or after the Target Injection Date¹
 - Point of contact for any concerns, side effects or appointment changes
- Identify clear roles and responsibilities
 - Management of LAI training
 - Ventrogluteal injection administration (see QR code for video)
 - Identifying and counselling patients

Service delivery:

- Build a standard operating procedure (SOP), PrEP multidisciplinary team (MDT) for LAI, and patient pathway
- Ensure access to the Medicines Procurement and Supply Chain (MSPC) and Blueteq
- Consider management of results and appointments
- Special considerations (refer to Summaries of Product Characteristics):^{1,2}
 - HIV testing at each injection visit
 - Consider using 2-inch needle for patients with $BMI \geq 30\text{kg}/\text{m}^2$
 - Gluteal implants
 - Hepatitis B status/immunity⁴
 - Pregnancy
 - Other intramuscular (IM) injections at the site
 - Assess for potential drug-drug interactions (DDIs) with current and future medications
- Liaise with pharmacy: Formulary access, medicines ordering, reporting, and safe storage
- Risk minimisation materials (see QR code)

People who would benefit from PrEP

- Shared decision-making: Inform individuals of cabotegravir for PrEP, involve them in decisions for their care, and uncover their reasons why they cannot have oral PrEP including social and personal circumstances⁵
- Ensure clinical space is equipped for administering injections eg: privacy
- Sharing information with individuals: appointment schedule, importance of adherence, cancelling appointments in good time, planning travel or life events, injection site reactions, managing pain, and risk of resistance



Scan QR code to visit
Ventrogluteal Injection
Administration
(video)



Scan QR code to visit
Injection Scheduling
Tool



Scan QR code to visit
Example of
Clinical Process Flow



Scan QR code to visit
Risk Minimisation Materials
including prescriber checklist,
prescriber guide, user guide
and reminder card



Scan QR code to visit
NHS England Guidance for
Shared-decision Making



Scan QR code to visit
BASHH toolkit supporting provi-
sion of complex PrEP in England



IMPLEMENTATION

Clinical guidance:

- Individuals must be tested for HIV-1 prior to initiating cabotegravir and at each subsequent injection of cabotegravir
- A combined antigen/antibody test as well as an HIV-RNA-based test should both be negative
- Perform both tests, even if the result of the HIV-RNA-based test will become available after cabotegravir injection
- If a combined testing strategy including both tests is not available, testing should follow local guidelines
- Oral lead-in for cabotegravir as PrEP should be optional for people worried about side effects
- Refer to SmPC (see QR codes) for managing missed doses and oral bridging
- Embed active recall systems to support adherence with on time injections
- Ventrogluteal injection site recommended as best practice
- If discontinuing cabotegravir injections, account for its prolonged release and consider alternative PrEP options for those still needing HIV prevention



Scan QR code to visit
**Summary of Product Characteristics (SmPC)
for Cabotegravir for PrEP (Apretude) 600 mg
prolonged-release suspension for injection**



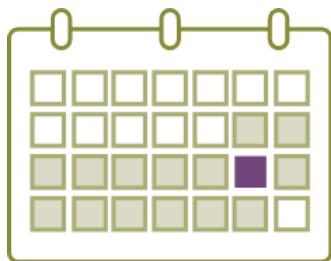
Scan QR code to visit
**Summary of Product Characteristics
(SmPC) for Cabotegravir for PrEP
(Apretude) 30 mg film-coated tablets**



Scan QR code to visit
**Resources for healthcare
professionals**

Clinic appointments and educational materials

- First appointment discussion: Injection schedule, techniques for managing injection site reactions including pain, and HIV testing
 - The optional oral lead-in can be discussed to assess tolerability prior to injection administration
- The first two initiation injections are one month apart, followed by continuation injections every 2 months
- Ongoing 2-monthly injection appointments may take less time as patients become more informed and HCPs grow in confidence
- ± 7 -day window: Refer to SmPC (see QR codes) for managing missed doses, oral bridging, and time to protection
- Discussions at each appointment:
 - Changes in medication, general health or body weight
 - Pregnancy
 - Ongoing discussion about reasons for HIV prevention and any additional health needs
 - Adherence to injection schedule
 - Monitoring for side effects



Target injection date with
 ± 7 -day window





TOP TIPS

1. Offer flexibility of appointment, where able, to support adherence
2. Start small, consider a database and form a multidisciplinary working group
3. Consider scheduling appointments for the year to support planning ahead
4. Communication and engagement are key
5. Multiple methods of contact to change appointment
6. Ventrogluteal – use training resources, work with practice development, and appoint a rollout champion
7. Utilise your national network and best practice sharing sessions
8. Revisit patient education regularly including risk minimisation materials (user guide and reminder card)
9. Service sustainability: Train other HCPs within your clinic to help with flexibility and capacity
10. Access top tips from community of practice infographics (see QR codes)



Scan QR code to visit
Community of Practice 2024
Infographic



Scan QR code to visit
Community of Practice 2025
infographic

CLINICAL COLLABORATORS



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To join the **monthly ViiV Healthcare virtual best practice sharing meetings**,
please contact Shaun or Liz at UK_NA@viivhealthcare.com



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Special thanks to the original authors of the guide from which this document
has been adapted: Christina Casley, Michelle Croston, Jonathan Roberts, and
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**Please scan the QR code to access
cabotegravir[▽] for PrEP
prescribing information and adverse
event reporting**

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GSK via the [GSK Reporting Tool](#) or on 0800 221441

References:

1. APRETUDE[▽] (cabotegravir) 600 mg suspension for injection Summary of Product Characteristics (SmPC)
2. APRETUDE[▽] (cabotegravir) 30 mg film-coated tablets Summary of Product Characteristics (SmPC)
3. British Association for Sexual Health and HIV (BASHH) / British HIV Association (BHIVA) guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2025
4. European AIDS Clinical Society (EACS) Guidelines 13.0 2025
5. NICE technology appraisal guidance TA1106. Available at: <https://www.nice.org.uk/guidance/ta1106> Accessed Nov 2025