

# Oral and Long-Acting Injectable Cabotegravir Preexposure Prophylaxis Use Among U.S. Veterans Using Veterans Health Administration Services, 2021-2025 (306339)

**First published:** 19/02/2026

**Last updated:** 18/03/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000939

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### Study ID

1000000939

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### DARWIN EU® study

No

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### Study countries

United States

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### ViiV Healthcare

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Contact details

#### Study institution contact

Call Center ViiV Healthcare Company RD.CTT-  
globalmailbox@gsk.com

Study contact

[RD.CTT-globalmailbox@gsk.com](mailto:RD.CTT-globalmailbox@gsk.com)

#### Primary lead investigator

Call Center ViiV Healthcare Company

Primary lead investigator

### Study timelines

**Date when funding contract was signed**

Actual: 15/09/2025

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### **Study start date**

Planned: 25/02/2026

Actual: 23/02/2026

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### **Date of final study report**

Planned: 30/09/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare Company

## Study protocol

[306339\\_VACS\\_oral\\_CAB LA PrEP\\_Final Protocol-Anonymised 05 Feb 2026.pdf](#)

(662.97 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

Non-interventional study

**Main study objective:**

- Objective Set 1: Estimate annual HIV diagnosis rates among Veterans in care and describe the history of PrEP use among newly diagnosed HIV patients.
- Objective Set 2: Characterize Veterans not on PrEP but who could benefit from it and evaluate rates of HIV/STI testing and diagnoses over 12 months.
- Objective Set 3:
  - Describe demographic, clinical and sexual behavioral characteristics of Veterans initiating oral or cabotegravir long-acting (CAB LA) PrEP.
  - Estimate the proportion of CAB LA PrEP users initiating PrEP with oral lead-in (OLI) versus direct-to-injection (DTI).
  - Describe adherence to oral PrEP and CAB LA injectable PrEP.
  - Describe patterns of PrEP use, including discontinuation, resumption, and duration of use for both oral and CAB LA PrEP.

- Describe HIV and STI testing, diagnoses, and antimicrobial treatment prescription for STI by PrEP modality.
- For CAB LA PrEP users diagnosed with HIV, analyze the timing of HIV diagnoses relative to PrEP usage, injection schedules, HIV treatment, virologic suppression, STI diagnoses, and HIV drug resistance.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

APRETUDE

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### **Medicinal product name, other**

Cabotegravir

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### **Study drug International non-proprietary name (INN) or common name**

CABOTEGRAVIR

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### **Anatomical Therapeutic Chemical (ATC) code**

(J05AJ04) cabotegravir

cabotegravir

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### **Medical condition to be studied**

HIV infection

## Population studied

## Short description of the study population

Veterans in care, 18 years or older without evidence of HIV infection at index date.

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### Age groups

- **Adult and elderly population ( $\geq 18$  years)**
    - Adults (18 to < 65 years)
      - Adults (18 to < 46 years)
      - Adults (46 to < 65 years)
    - Elderly ( $\geq 65$  years)
      - Adults (65 to < 75 years)
      - Adults (75 to < 85 years)
      - Adults (85 years and over)
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### Estimated number of subjects

0

## Study design details

### Setting

The data used will be extracted from VHA's Corporate Data Warehouse (CDW), a comprehensive, continually updated repository of information from VHA's electronic health records (EHR) and administrative files.

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### Comparators

Not Applicable

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### Outcomes

1. Yearly incidence proportion of HIV diagnoses among individuals in Veterans Health Administration (VHA) care and history of PrEP use among incident HIV cases
  2. Characteristics of individuals in VHA care without evidence of HIV infection who are not on PrEP but could benefit from PrEP
  3. Incidence proportions and rates of HIV testing and diagnoses, and STI screening/testing and diagnoses among individuals in VHA care who are not on PrEP but could benefit from PrEP
  4. Demographic, clinical and sexual behaviour characteristics of individuals in VHA care with no evidence of HIV infection who initiate PrEP (oral or CAB LA injectable) during the study period
  5. Adherence to oral and CAB LA injectable PrEP (proportion of days covered, timing and completion of injections), proportion of CAB LA PrEP users with oral lead in (OLI) or direct to injection (DTI)
  6. Patterns of oral PrEP and CAB LA PrEP use
  7. Patterns of HIV and other STI testing/screening, diagnosis and STI treatment among individuals in VHA care initiating PrEP
  8. HIV testing history, timing of CAB LA injections, HIV treatment prescribed, viral load measurement timings and results, concomitant STI diagnosis, and HIV drug resistance testing results among CAB LA PrEP users diagnosed with HIV
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### **Data analysis plan**

All analyses in this study will be descriptive, focusing on estimating frequencies of outcomes across various objectives.

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### **Summary results**

All data analyses will be computed in a descriptive manner. Results will be published via study reports.

## Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s)

Other data source

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### Data source(s), other

US Veterans Health Administration (VHA) Corporate Data Warehouse

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Electronic healthcare records \(EHR\)](#)

[Laboratory tests and analyses](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown