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

Study ID

1000000939

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

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

Study contact

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Primary lead investigator

Call Center ViiV Healthcare Company

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/09/2025

Study start date
Planned: 25/02/2026

Actual: 23/02/2026

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

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

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

Medicinal product name, other

Cabotegravir

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

CABOTEGRAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AJ04) cabotegravir

cabotegravir

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.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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.

Comparators

Not Applicable

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

Data analysis plan

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

Summary results

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

Data management

ENCePP Seal

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

Data source(s), other

US Veterans Health Administration (VHA) Corporate Data Warehouse

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown