GLACIER

Protocol 214747

A Post-Approval CABENUVA Implementation Study

Sponsored by ViiV Healthcare

This presentation is intended for healthcare professionals.

Protocol 214747

Title: A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers (ICs)

The intention of this post-approval study is to evaluate the acceptability and feasibility of using ICs to administer CABENUVA treatments.

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CABENUVA

- FDA-approved treatment for HIV-1, commercially available in the United States
- 2-drug co-packaged product of cabotegravir plus rilpivirine, both administered as long-acting (LA) intramuscular (IM) injections
- Administered as two IM injections by a healthcare professional once every month or once every 2 months

Please visit **https://cabenuvahcp.com/** for more information**.**

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Delivery of CABENUVA Treatment

- An expanded capacity for delivery of CABENUVA treatment is needed to
  - Accommodate the anticipated increase in visits
  - Assist with processing insurance for patients
  - Administer injections once every month or once every 2 months
- The use of ICs has the potential to:
  - Help ease the burden on HIV providers and their staff
  - Expand availability of CABENUVA treatment

Referring HIV care providers will maintain medical oversight of their patients.

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Infusion Centers

Infusion centers are a natural option for administering CABENUVA treatment, as they:

- Routinely administer injectable treatments to a diverse patient population
- Have trained medical staff onsite
- Can help manage the insurance approval process
- Have existing infrastructure to support communication between the IC, people living with HIV, and HIV care providers/clinical staff

Additionally, these centers are not diagnosis specific, which allows for an added level of privacy during treatment appointments.

Implementation Blueprint

- Establishes best practices and standard operating procedures for the administration of CABENUVA treatment at ICs, per the United States Prescribing Information (USPI)
- Ensures optimal communication between ICs, people living with HIV, and HIV care providers/clinical staff
- Supports continuity of care as referring providers maintain medical oversight of their patients

Implementation Measurements

The GLACIER study is measuring the acceptability and feasibility of using ICs to administer CABENUVA treatments from the perspectives of participants, referring HIV care providers/clinical staff, and IC staff. This will be done using the following tools:

- Feasibility of Intervention Measure (FIM)
- Acceptability of Intervention Measure (AIM)
- Additional quantitative questionnaires
- Qualitative interviews (for select participants)

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Study Design

- Up to 120 participants
- Approximately 8 months total study duration for each participant
- CABENUVA injections administered to participants at ICs once a month or once every 2 months, as prescribed by their HIV care provider, per the USPI
- Participants monitored according to usual standard care at their physician's discretion; HIV care providers maintain medical oversight of their patients

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Study Population (Key Eligibility Criteria)

- ≥18 years old
- HIV-1 infected and prescribed CABNEUVA per the USPI
- Agreement to receive CABENUVA IM injections at a participating IC
- No contraindicated or prohibited co-administered drugs, as per the CABNEUVA USPI

Full inclusion and exclusion criteria apply.

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Costs and Resources

People living with HIV who are prescribed CABENUVA can be enrolled in ViiVConnect to get help with:

- Understanding the insurance process, which the ICs will help manage
- Checking eligibility for savings or assistance programs*

**Subject to eligibility and program terms and conditions; ViiVConnect programs do not constitute health insurance.*

Resources

- ViiVConnect.com or 1-844-588-3288 (toll-free), Monday-Friday, 8AM-11PM (ET)
- https://cabenuvahcp.com/
- https://www.cabenuva.com/
- https://clinicaltrials.gov/ct2/show/NCT04982445

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Summary

- Expanding availability of CABENUVA treatment is important to ensure that those who want this FDA-approved treatment have access to it in a way that works for them and their HIV-1 healthcare providers.
- The use of ICs has the potential to help ease the burden on HIV specialty clinics and provide people living with HIV greater flexibility in where they receive their CABENUVA injections.
- During this study, participants will receive their prescribed CABENUVA treatment at a participating IC.
- Questionnaires and interviews will be used to assess acceptability and feasibility from the perspectives of participants, referring HIV care providers/clinical staff, and IC staff.

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Referrals

As noted previously, referring providers will maintain medical oversight of their patients. For more information about the study or to refer a patient, please contact glacierhivstudy@mmgct.com

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