# Cabenuva (cabotegravir & rilpivirine extended-release injections)
# Considerations for AIDS Drug Assistance Programs
# March 2022

ViiV Healthcare's Cabenuva – copackaged cabotegravir and rilpivirine extended-release injectable suspensions – was approved by the U.S. Food and Drug Administration on January 21, 2021. Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen, with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

This novel antiretroviral therapy option may help to alleviate pill fatigue, maintain long-term adherence, reduce stigma associated with taking oral medications, and improve quality of life for some people living with HIV. Access for Ryan White HIV/AIDS Program Part B (RWHAP Part B) AIDS Drug Assistance Program (ADAP) clients may, however, require program policy and procedural adjustments associated with the procurement and payment of provider-administered drugs.

## GENERAL CONSIDERATIONS

### Clinical Considerations

- Prior to initiating Cabenuva as maintenance therapy, patients will need to be virally suppressed on a stable oral regimen, with no known or suspected resistance to either cabotegravir (an integrase strand transfer inhibitor) or rilpivirine (a non-nucleoside reverse transcriptase inhibitor).
- **Oral lead-in dosing** with Vocabria (30 mg cabotegravir) and Edurant (25 mg rilpivirine) used for one month to assess the tolerability of cabotegravir and rilpivirine *is now optional*. Thirty-day supplies of Vocabria and Edurant will be provided by ViiV Healthcare through a non-commercial dispensing pharmacy without cost to the patient, provider, or payer (including ADAP); see Page 4 for additional details. Vocabria will not be available from community/retail pharmacies.
- **Cabenuva initiation dosing** requires two 3 mL IM injections (600 mg cabotegravir plus 900 mg rilpivirine), administered at separate gluteal injection sites during the same visit.
- **Cabenuva continuation dosing** involves either of the following:
    - Two 3 mL gluteal IM injections (600 mg cabotegravir plus 900 mg rilpivirine) administered every two months; *or*
    - Two 2 mL gluteal IM injections (400 mg cabotegravir plus 600 mg rilpivirine) administered every month

- Continuation injections should be initiated a month after the initiation injections. There is a 14-day window for receiving injections – either 7 days before or 7 days after the target treatment date.
- If injections are planned to be missed or delayed by more than seven days, clients should discuss with their health care providers oral "bridging" therapy – e.g., oral therapy of one Vocabria tablet (to be requested via ViiVConnect) plus one Edurant tablet until the next injection can be administered – until injections can be restarted.
- 48-week data from the Phase III FLAIR study, ATLAS study and ATLAS-2M study demonstrating Cabenuva's safety and efficacy as maintenance therapy with intramuscular dosing every four and eight weeks have been published.
- Additional clinical considerations are available via the FDA-approved package insert for Cabenuva, as well as the U.S. Department of Health and Human Services' *Adults and Adolescents Antiretroviral Guidelines Panel Recommendation for the Long-Acting Injectable Antiretroviral Regimen of Cabotegravir and Rilpivirine*.


Left: Cabenuva initiation dosing (600 mg/900 mg) kit. NDC: 49702-0240-15
Right: Cabenuva continuation dosing (400 mg/600 mg). NDC: 49702-0253-15

**Delivery System Considerations**

- Cold-chain supply and storage (2°C to 8°C; 36°F to 46°F) will be required. Cabenuva will need to be brought to room temperature (removed from refrigerator for ≥15 minutes) and used within six hours. If not used within six hours, the medication must be discarded. Cabotegravir and rilpivirine can remain in syringes for up to two hours before injecting. If two hours are exceeded, the medication, syringes, and needles must be discarded.
- Each Cabenuva dosing kit contains one vial each of cabotegravir and rilpivirine plus vial adaptors, syringes, and 23-gauge needles.

- Cabenuva is approved for gluteal intramuscular use only. Cabotegravir and rilpivirine injections at separate ventrogluteal sites (on opposite sides or at least 2 cm apart) using the Z-track method is recommended.
- Cabenuva Injections will require administration in a private space in a clinic or possibly a pharmacy.
- Clinics will need to assess available clinic space and develop staffing plans to accommodate more frequent office visits for patients receiving Cabenuva.
- More intensive patient reminder systems will likely be needed to ensure patients do not miss a monthly injection.

**Procurement Considerations**

- As a provider-administered drug with cold-chain requirements, Cabenuva is available under a limited distribution model. It is typically procured through "buy-and-bill", "white bagging" or "clear bagging" (see side bar).
- Cabenuva is currently available via buy-and-bill from the following **specialty distributors**: ASD Specialty Healthcare, Besse Medical, Cardinal Health Specialty, Curascript Specialty Distribution, McKesson Plasma and Biologics, McKesson Specialty Health, McKesson Medical-Surgical, and Oncology Supply.
- Cabenuva is currently available via white-bag mechanisms from the following **specialty pharmacies:** Accredo Health Group, Inc, AHF Pharmacy, Coordinated Care Network, Curant Health, CVS Specialty, Diplomat (Optum), Fairview Specialty, Humana Specialty Pharmacy, Kroger Specialty Pharmacy, Longs/Avita Specialty, Mail-Meds Clinical Pharmacy, Meijer Specialty, Optum/Avella, Walgreens/AllianceRx Prime.
- A **wholesaler network** for Cabenuva has also been established, which includes AmerisourceBergen Corporation, Cardinal Health, McKesson Corporation, Morris and Dickson Company, and multiple other wholesalers that service eligible customer classes of trade.

**Buy-and-Bill**: Provider or clinic purchases Cabenuva from a specialty distributor and maintains an inventory of the drug for use on an as-needed basis. Following administration of the drug to a patient, the provider submits a reimbursement claim to the patient's public or private insurance carrier.

**White Bagging**: Provider submits prescription for Cabenuva to a specialty pharmacy within ViiV's (and the ADAP's) specialty pharmacy network. The specialty pharmacy processes the claim and ships product to the provider. Once the Cabenuva is received by the provider, it can only be administered to the patient prescribed the drug.

**Clear Bagging**: A health system's internal specialty pharmacy maintains inventory of Cabenuva, processes the claim when a prescription is received from a health system provider, and then delivers the medication in time for the patient's administration appointment.

## AIDS DRUG ASSISTANCE PROGRAM CONSIDERATIONS

### General Formulary and Coverage Considerations

- Neither cabotegravir nor rilpivirine constitute a drug or biologic from a new class of antiretroviral medications. In turn, Cabenuva is not required to be added to ADAP formularies, as per requirements under Section 216(c) of the Public Health Service Act.
- A December 2019 HRSA HAB Program Letter recommends ADAPs consider adding long-acting ARVs to their formularies.
- The Program Letter also states that it is allowable for ADAPs to pay for the cost of administering an ARV on their formularies, including the cost of an office visit exclusively for medication administration. For ADAP-funded insurance clients, the letter allows for coverage of cost-sharing related to provider administration of ARV drug or biological products.
- ViiVConnect will serve as a hub for Cabenuva procurement. Following electronic or fax submission of an enrollment form, ViiVConnect can coordinate and support coverage verifications (including with state and territorial ADAPs). ViiVConnect can also provide support to patients and providers with prior authorization requests, insurance claims and denials appeals, and cost-sharing assistance for insured clients.
    - A patient assistance program (PAP) for uninsured patients (and Medicare clients who have paid out more than $600 in cost sharing associated with Cabenuva) can also be access via ViiVConnect. The PAP is not available to ADAP clients.
- The optional oral lead-in medications (Vocabria and Edurant) can be accessed via ViiVConnect and are shipped by a contracted non-commercial pharmacy (TheraCom Pharmacy) once insurance coverage for Cabenuva has been verified and/or authorized. Oral lead-in doses can also be secured directly from TheraCom Pharmacy (General Phone: 1-877-654-7812; General Fax: 1-844-773-1422; ViiV Specific Team Phone: 1-844-276; ViiV Specific Team Fax: 1-833-904-1881).

**Full-Pay Program Considerations**

- As a primary payer for eligible people living with HIV, ADAPs may choose how to procure and/or cover Cabenuva for their full-pay programs, in alignment with their direct purchase and/or rebate mechanism(s):
    - **Direct Purchase ADAP:** Direct-purchase ADAPs can procure Cabenuva via an authorized wholesaler or specialty distributor (see Page 3) at the ADAP Crisis Task Force-negotiated sub-340B price, or establish bill-to/ship-to replenishment with an eligible 340B contract pharmacy. Cabenuva is shipped to provider for administration to the ADAP client.
    - **Rebate ADAP (White-Bag Distribution Model):** ADAP requires Cabenuva prescriptions to be filled by contract or PBM network specialty pharmacy (see Page 3) that is part of the Cabenuva specialty pharmacy network. The specialty pharmacy ships product to provider for administration to ADAP client, and invoices ADAP or vendor (e.g., medical benefit manager) for the product. ADAP reimburses the specialty pharmacy and then files a rebate claim with manufacturer.
    - **Rebate ADAP (Buy-and-Bill Distribution Model):** ADAP establishes a network of providers that may draw on their own inventory of Cabenuva, with invoices submitted to ADAP or vendor (e.g., medical benefit manager) at a contracted rate (e.g., Average Wholesale Price – X%, Average Sales Price + X%, 340B discounted acquisition cost + X%, etc.). ADAP reimburses the provider and then files a rebate claim with manufacturer.
- Providers may seek reimbursement from ADAP for the injection administration service and/or an office visit fee, regardless of which of the above methods was used by the provider to acquire Cabenuva.
    - Where a **direct purchase** or **white-bag rebate mechanism** is used and payment for the medication is made to the wholesaler, specialty distributor, or specialty pharmacy, a separate claim (e.g., CMS Form 1500) from a provider may include allowable administration or office visit costs.
    - Where **a buy-and-bill rebate mechanism** is used, a claim (e.g., CMS Form 1500) from a provider will include the allowable cost of the medication plus any allowable administration or office visit costs.
    - In accordance with the HRSA HAB Program Letter referenced above, ADAPs may use federal dollars (or rebates) to cover antiretroviral drug product administration and office visit costs. The RWHAP Part B program Outpatient/Ambulatory Health Services (OAHS) service category may also be used. Where ADAPs choose to cover these costs, payment rates may be negotiated with providers.
    - See Appendix for a Cabenuva billing, coding, and administration/office visit payment reference.

**ADAP-Funded Insurance Program**

- Due to Cabenuva's administration in a clinical setting, health insurers are likely to cover it as a medical benefit. Insurers may also cover it as a pharmacy benefit, or as both a medical and pharmacy benefit.
- Cost-sharing requirements will depend on how Cabenuva is covered:
    - Drugs covered as a medical benefit by **individual, small group, or large group commercial plans** often require a flat co-insurance rate (e.g., 20% of the total cost of the medication), typically after the plan deductible requirement has been met.
    - For **Medicare** clients, Cabenuva is expected to be covered under Part B as a provider-administered drug. Under Medicare Part B, the beneficiary may be responsible for up to 20% of the medication cost after the deductible requirement has been met; supplemental insurance coverage, Medicaid dual-eligibility, or enrollment in the Qualified Medicare Beneficiary (QMB) program may defray cost-sharing requirements. Some Medicare Advantage plans that include prescription drug coverage (Part D) may opt to cover it as a pharmacy benefit.
    - State **Medicaid** programs must cover Cabenuva, but cost-sharing and utilization management (e.g., prior authorization) requirements may vary by state. Cost-sharing is typically nominal.
- In accordance with the HRSA HAB Program Letter referenced above, ADAPs may use federal dollars (or rebates) to cover the cost sharing associated with Cabenuva injections; the RWHAP Part B program Health Insurance Premium & Cost Sharing Assistance for Low-Income Individuals service category may also be used.
- ADAPs that have added Cabenuva to their formularies are encouraged to inform ViiVConnect of their ADAP-funded insurance policies and cost-sharing (deductible, copayment, or coinsurance, including for where Cabenuva is covered as a medical benefit or pharmacy benefit) claim submission and payment procedures. ADAPs are also encouraged to instruct ADAP-funded insurance clients, or their provider representatives (e.g., case managers), to inform ViiVConnect of ADAP cost-sharing support at the time of enrollment in the program.
    - Based on expenditure and rebate forecasting, ADAPs may wish to defer coverage of Cabenuva cost sharing associated with individual or employer-sponsored commercial plans to ViiVConnect's Patient Savings Program. ViiV is offering assistance of up to $13,000 per year (including up to $100 on cost-sharing assistance with Cabenuva injection administration fees) to help cover commercial insurance cost-sharing requirements associated with Cabenuva.

Please contact Tim Horn, Director, Health Care Access, with any questions or additional technical assistance needs.

**APPENDIX**
**Cabenuva Billing and Coding Reference**

Most payers require specific coding in claims for provider-administered drugs. These include the Healthcare Common Procedural Coding System (HCPCS) J-codes, National Drug Codes (NDCs), International Classification of Diseases (ICD) codes, and Current Procedural Terminology (CPT) codes. The relevant codes for Cabenuva are described here:

| Code Category | Code Number | Description |
|---|---|---|
| NDC | 49702-240-15 | Cabenuva 600 mg/900 mg kit (initiation injections) |
| | 49702-253-15 | Cabenuva 400 mg/600 mg kit (continuation injections) |
| ICD-10 | B20 | Human immunodeficiency virus (HIV) disease |
| | Z21 | Asymptomatic HIV infection status |
| CPT | 96372 | Therapeutic, prophylactic, or diagnostic injection (SQ or IM) |
| HCPCS | J0741 | Injection, cabotegravir and rilpivirine, 2mg/3mg |

Whereas a J-code is typically associated with the allowable cost of the medication (e.g., ASP + 6%, acquisition cost + X%, etc.) where buy-and-bill is used by providers, it may also be included on claims where the medication was procured via a white-bag mechanism. Billing units are based on which Cabenuba kit was administered to the patient:

- One 4 mL 400-mg/600-mg kit (NDC: 49702-253-15) = 200 billing units
- One 6 mL 600-mg/900-mg kit (NDC: 49702-240-15) = 300 billing units

Example 2022 Medicare Physician Fee Schedule (MPFS) payments for procedure and office visit codes relevant to the administration of Cabenuva are described here:

| CPT Code | Description | Medicare National Payment – 2022 Final Rates |
|---|---|---|
| 96372 | Therapeutic, prophylactic, or diagnostic injection (SQ or IM) | $14.54 |
| 99211 | Office or other outpatient visit, existing patient, minimal problems | $23.53 |
| 99212 | Office or other outpatient visit, existing patient, straightforward 10-19 minutes | $57.54 |
| 99213 | Office or other outpatient visit, existing patient, low complexity 20-29 minutes | $92.05 |
| Actual provider rates will vary according to the type and geographic location of the provider.<br>When a patient receives two injections – Cabenuva requires two IM injections – some providers may include two line items using CPT 96372 (with the second CPT 96372 containing a modifier to note it as a distinct procedural service. | | |