



Preparing for Long-Acting Antiretroviral Treatment February 2021

ViiV Healthcare's Cabenuva – cabotegravir extended-release injectable suspension co-packaged with rilpivirine extended-released injectable suspension – was [approved](#) by the U.S. Food and Drug Administration on Jan. 21. Cabenuva is indicated as a complete maintenance therapy option for people living with HIV who are virologically suppressed on a stable antiretroviral regimen, with no history of treatment failure or suspected resistance to either cabotegravir or rilpivirine.

This novel maintenance therapy option may help to alleviate pill fatigue, improve adherence, and reduce stigma for some patients, but will require pharmacy and clinical delivery system and administrative adjustments for clinics and providers.

This document highlights delivery system, staffing and administrative issues for clinics and clinicians to consider in preparing to provide patients access to this novel treatment modality. Please see the Cabenuva [package insert](#) for more detailed information on clinical considerations and detailed instructions for use.

Clinical Considerations

- 48-week data from the Phase III [ATLAS study](#) and [FLAIR study](#), demonstrating Cabenuva's safety and efficacy as maintenance therapy with intramuscular dosing every four weeks, have been published in the *New England Journal of Medicine*.
- Patients will need to be virally suppressed on a stable oral regimen, with no known or suspected resistance to either cabotegravir or rilpivirine, prior to initiation.
- Prior to initiating treatment with Cabenuva, oral lead-in dosing with Vocabria (30 mg cabotegravir) and Edurant (25 mg rilpivirine) should be used for approximately one month to assess the tolerability of cabotegravir and rilpivirine. Vocabria and Edurant should be taken once daily with food (two tablets once daily). Thirty-day supplies of Vocabria and Edurant will be provided, without cost to patients, providers, or payers, by ViiV Healthcare. Vocabria will not be available from pharmacies.
- The Cabenuva loading dose requires two 3 mL IM injections (600 mg cabotegravir plus 900 mg rilpivirine).
- Maintenance dosing, involving two 2 mL IM injections (400 mg cabotegravir plus 600 mg rilpivirine), will be required monthly. There is a 14-day window for receiving injections – either 7 days early or 7 days late.
- Maintenance dosing administration every eight weeks, involving two 3 mL IM injections, is being evaluated in the [ATLAS-2M clinical trial](#), with 48-week data published in *The Lancet*. A supplemental New Drug Application, to be filed by the manufacturer, is forthcoming.

- If monthly injections are missed or delayed by more than seven days, according to the recommendations approved by the FDA, the oral daily bridging regimen is one Vocabria tablet plus one Edurant tablet. If two months or less have passed since the last injection, 400 mg cabotegravir and 600 mg rilpivirine monthly injections should be resumed as soon as possible. If more than two months have passed since the last injection, reinitiating injections with 600 mg cabotegravir and 900 mg rilpivirine is recommended, followed by a return to 400 mg cabotegravir and 600 mg rilpivirine monthly injection schedule.

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) for up to 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.**
- Each Cabenuva package contains one vial each of cabotegravir and rilpivirine plus vial adaptors, syringes, and 23-gauge needles. The packages measure 6.2 inches W x 5.6 inches D x 1.7 inches H. It is estimated that a 4.5 cu ft mini fridge holds 24 boxes.
- Cabenuva is approved for gluteal intramuscular use only. Cabotegravir and rilpivirine Injections at separate ventrogluteal or dorsogluteal sites (on opposite sides or at least 2 cm apart) using the Z-track method is recommended and generally 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.
- State regulations or a clinic or institution's internal policies may determine who can administer the injection. Nurses or other staff able to administer the injection may require training.
- More intensive patient reminder systems will likely be needed to ensure patients do not miss a monthly injection. The ViiVConnect hub can assist with these reminders (see sidebar).

ViiVConnect Hub

ViiV Healthcare's hub, ViiVConnect, provides [Cabenuva-specific support services](#) for providers and people living with HIV. ViiVConnect will coordinate and support coverage verification, prior authorization support, claims and denials appeals support, cost-sharing assistance for insured clients, introductory packets (including Vocabria and Edurant dispenses for lead-in dosing), patient assistance for uninsured or other eligible clients, tailored case management, and injection appointment reminders. Access to Cabenuva with ViiVConnect coordination begins with the submission of a patient enrollment form.

Healthcare Coverage

- Due to Cabenuva's administration in a clinical setting, health insurers are likely to cover it as a medical benefit, which will affect how clinics procure, and bill for, the products. Insurers may also cover it as a pharmacy benefit, or as both a medical and pharmacy benefit.

- Patients' out-of-pocket costs will be determined by how the medication is covered.
- Drugs covered under the health insurer's medical benefit often require a flat co-insurance rate (e.g., 20% of the cost of the injections).
- For Medicare clients, Cabenuva is expected to be covered under Part B as a provider-administered drug. Some Medicare Advantage plans (with Part D coverage) may opt to cover it as pharmacy benefit, however.
- Medicaid coverage policies will be determined on a state-by-state basis.
- For bridging doses, ViiV will supply Vocabria for a planned missed dosage and patients will need to fill a prescription for Edurant (rilpivirine) from their regular pharmacy or access it through Johnson & Johnson's [patient assistance program](#).

Procurement and Purchasing

- Drugs administered by a clinician, particularly those with cold-chain requirements, are generally not available through retail pharmacies. They are typically procured through one of the options below.
 - Buy-and-bill: Provider or clinic purchases the drug/biologic product from a wholesaler or specialty distributor and bills the primary third-party payer. Provider or clinics assume liability for the cost of the drug under this model. Buy-and-bill is typical of drugs or biologics covered as a medical benefit.
 - White bagging: Provider submits prescription to a specialty pharmacy within ViiV's specialty pharmacy network (see below); specialty pharmacy processes the claim and ships product to the provider for administration. White bagging is typical of drugs or biologics covered as a pharmacy benefit.
- Temperature-controlled storage will be needed for Cabenuva.
- Separate buy-and-bill and white-bag inventories will need to be maintained.
- Cabenuva is currently available via buy-and-bill and white-bag mechanisms from the following **specialty pharmacies and distributors**: Accredo Health Group, Inc, AHF Pharmacy, ASD Healthcare, Besse Medical, Cardinal Health Specialty, Coordinated Care Network, Curant Health, CuraScript Specialty Distribution, CVS Specialty, Diplomat (Optum), Fairview Specialty, Humana Specialty Pharmacy, Kroger Specialty Pharmacy, Optum/Avella, AllianceRx Walgreens Prime, Longs/Avita Specialty, Mail-Meds Clinical Pharmacy, McKesson Plasma and Biologics, McKesson Specialty Health, and Meijer Specialty.
- The following **wholesaler network** for Cabenuva has also been established: AmerisourceBergen Corporation, Anda, Cardinal Health, DMS Pharmaceutical Group, McKesson Corporation, Morris & Dickson Co., and Smith Drug Company.
- The procurement mechanism will primarily depend on the providers' preference and/or clients' insurance coverage (i.e., whether Cabenuva is covered as a medical benefit or pharmacy benefit, or where AIDS Drug Assistance Programs are the primary payer of medications for Ryan White HIV/AIDS Program clients living with HIV).

Ryan White HIV/AIDS Program Assistance

- Check with your state AIDS Drug Assistance Program regarding coverage of Cabenuva and the assistance that may be available. NASTAD maintains a [directory](#) of ADAP staff.
- The HIV/AIDS Bureau issued [guidance](#) in December 2019 recommending that AIDS Drug Assistance Programs add long-acting ARV products to their formularies when they become available. HAB also has determined that the costs of ARV product administration and/or office visits directly associated with provider administration of ARVs are allowable costs under the ADAP service category. In addition, ADAPs may cover medical co-payments associated with the administration of Cabenuva for patients with health insurance.
- Ryan White HIV/AIDS Programs may use the Outpatient/Ambulatory Health Services category to cover the costs associated Cabenuva administration where the Program is the primary payer of services (including where the state ADAP provides the medication); the Health Insurance Premium and Cost-Sharing Assistance for Low-Income Individuals category may be used to cover any primary payer cost-sharing assistance requirements.

Drug Cost Information

- The initial oral medication regimen is being provided free of charge by ViiV.
- The wholesale acquisition¹ cost of the initial (or loading dose) injections is \$5,940 per month.
- The wholesale acquisition cost of the monthly (maintenance) injections is \$3,960 per month.

Cost-Sharing and Patient Assistance

- Cabenuva is available at no cost to U.S. residents with household incomes of 500% of the [federal poverty level](#) or less, and either do not have prescription drug coverage or meet other insurance coverage-based criteria. ViiVConnect Patient Assistance Program (PAP) eligibility and enrollment details can be found [here](#).
- For individuals with commercial insurance prescription drug coverage, ViiV is offering assistance of up to \$13,000 per year (including up to \$100 on cost-sharing assistance with Cabenuva administration fees) to help cover the out-of-pocket prescription drug costs associated with Cabenuva through ViiVConnect's [Patient Savings Program](#). Access to the patient savings program is only available for patient enrolled through ViiVConnect.
- Assistance with out-of-pocket costs for Medicare beneficiaries is not available through ViiVConnect's Patient Savings Programs due to federal rules but may be available through state ADAPs.
- Details on patient and provider support services are available through [ViiVConnect](#) or by calling 1-844-588-3288 (toll free) Monday to Friday from 8am to 11 pm ET).

The information in this resource was compiled by the National Alliance of State and Territorial AIDS Directors and the HIV Medicine Association. Please email questions or comments to Tim Horn with NASTAD at thorn@nastad.org or Andrea Weddle with HIVMA at aweddle@hivma.org.

¹ The wholesale acquisition cost is the manufacturer's list price for the medication and does not take into account rebates or other discounts negotiated with third-party payers.