CABENUVA IMPLEMENTATION OVERVIEW

Preparing your practice for HCP-administered HIV therapy

Ashton, living with HIV.
Receiving CABENUVA.

Ashton has been compensated by ViiV Healthcare and is currently receiving CABENUVA.

INDICATION

CABENUVA is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Do not use CABENUVA in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine
- Do not use CABENUVA in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort

Please see additional Important Safety Information for CABENUVA throughout.
Please see accompanying full Prescribing Information for CABENUVA.

CABENUVA
cabotegravir 200 mg/mL; rilpivirine 300 mg/mL
extended-release injectable suspensions

Readying your practice for CABENUVA

CABENUVA is an HCP-administered specialty injectable. Specialty injectables are typically defined by their specific handling requirements, including precise temperature control, and may require additional clinical observation.[1] For some physicians, prescribing and administering CABENUVA may be a departure from typical practice patterns. As the HIV treatment paradigm is changing to include long-acting treatment, it is important to learn how to incorporate specialty injectable drugs into your practice.

This overview is designed to provide you with an introduction to:

3	Specialty injectable drugs
4	Payer coverage
5-6	Acquisition processes
7	CABENUVA prescribing pathways
8	Practice considerations for CABENUVA
9	Your CABENUVA support team

HCP=healthcare professional.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Hypersensitivity reactions, including cases of drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries
- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with CABENUVA
- Discontinue CABENUVA immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Cabotegravir and rilpivirine oral lead-in may be used to help identify patients who may be at risk of a hypersensitivity reaction

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What makes specialty injectables different?

The prescribing process for specialty injectables differs from traditional oral medication. Once a prescription for traditional oral medication is written, the patient is responsible for obtaining the medication from a retail pharmacy and taking it at home. Specialty injectables may require new and different processes, often including the integration of acquisition and administration into your practice.

There are 2 ways that you can acquire specialty injectables for your practice, which may depend on your patient's insurance coverage:

A SPECIALTY PHARMACY

A SPECIALTY DISTRIBUTOR

To determine how you will access specialty injectables in your practice, let's first discuss your patients' insurance coverage.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Post-Injection Reactions:

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). These events may have been associated with accidental intravenous administration and began to resolve within a few minutes after the injection
- Carefully follow the Instructions for Use when preparing and administering CABENUVA. The suspensions should be injected slowly via intramuscular injection and avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated

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How payers cover specialty injectables

Your patient may be insured through:

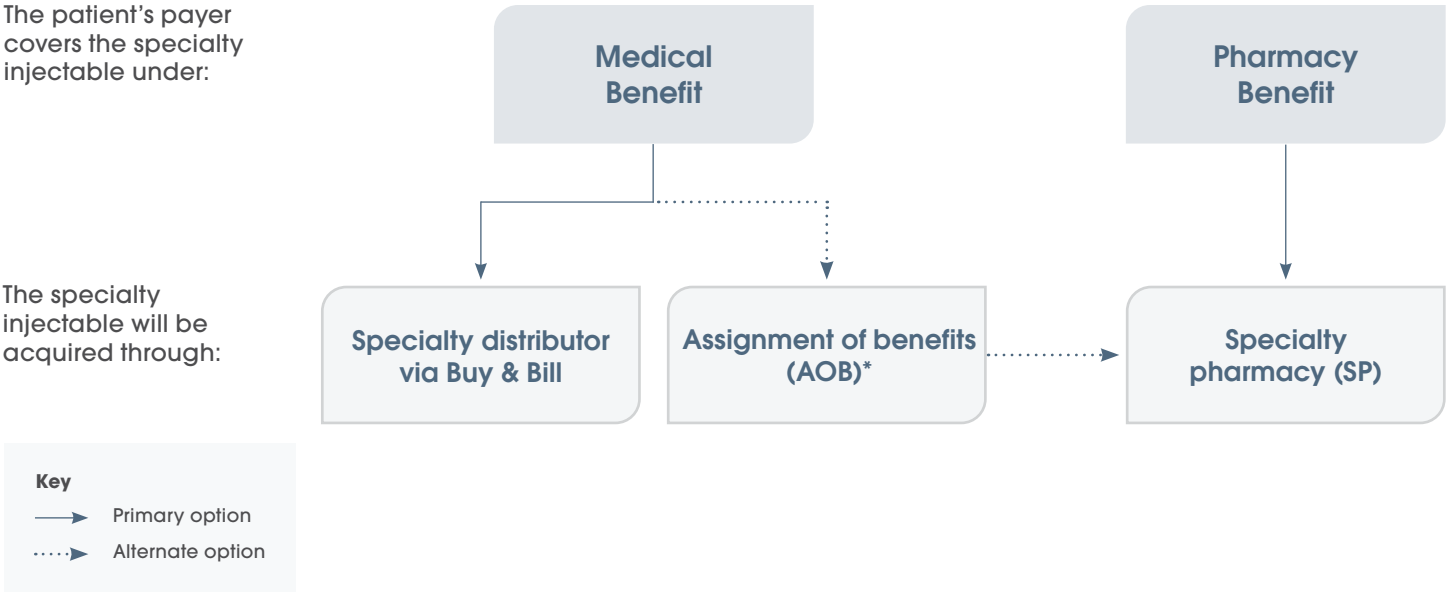
Commercial insurance

Medicare

Medicaid

Generally, payers tend to cover HCP-administered specialty injectables through a medical benefit. However, a payer may cover the product through a pharmacy benefit or a combination of the 2 benefits. How payers cover injectables may determine how you will acquire them.[1]

How to acquire a patient's specialty injectable



*An AOB is a process employed with a payer that will help determine if the specialty injectable can be sourced through a specialty pharmacy while covered under a medical benefit. The process varies widely by payer and, depending on your patient's coverage, is not always an option.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hepatotoxicity:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors
- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations
- Monitoring of liver chemistries is recommended and treatment with CABENUVA should be discontinued if hepatotoxicity is suspected

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Buy & Bill acquisition process

If your patient's insurance covers a specialty injectable under the medical benefit, then your office may decide to purchase the product from a specialty distributor and store the medication on the premises until you administer it. Once the product is administered, your practice will bill the patient's insurance for reimbursement. Although this requires some financial commitment up front, your practice can have CABENUVA readily available for appropriate patients without the administrative burden of coordinating with multiple specialty pharmacies.

Manage the entire acquisition process with Buy & Bill

1 Perform a benefits verification

Your practice will learn how the drug is covered, including if it requires a prior authorization or whether a predetermination is recommended.

2 Order specialty injectable from a specialty distributor

Your practice orders the drug and stores it on-site.

Assignment of Benefits (AOB)
Acquiring the drug from a specialty pharmacy may be possible using an Assignment of Benefits.

3 Schedule & administer the injections

Your practice collects the co-pay or coinsurance from each patient.

Alternate Site of Administration (ASA)
The administration of specialty injectables at an alternate site may be a more convenient option for you and/or your patients. When utilized, the ASA will conduct the benefits verification, acquire the medication, and collect the co-pay or coinsurance instead of your practice.

Up-to-date payer contracts and accurate coding are crucial for proper reimbursement. Be sure to verify payer coding requirements and ensure all your contracts are current.

Some common billing terms include:

- **J-code:** An HCPCS code that identifies injectable drugs
- **CPT code:** An American Medical Association code used to report procedures and services
- **Billing units:** The number of units of a product or service used

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Depressive Disorders:

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with CABENUVA or the individual products
- Promptly evaluate patients with depressive symptoms

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Specialty pharmacy acquisition process

If your patient's insurance covers a specialty injectable under the pharmacy benefit or an Assignment of Benefits was performed, then your office may acquire the product from a specialty pharmacy. It is important to consider that payers may have a preferred specialty pharmacy for the specialty injectable. Further, there is no option for in-office inventory because the specialty pharmacy only delivers the injectable on an individual patient basis.

Acquire medication through a specialty pharmacy

1 Perform a benefits verification

2 Submit a prescription

The choice of pharmacy may be dictated by the patient's insurance.

3 The specialty pharmacy ships the injectable

The pharmacy and your practice coordinate shipments to arrive in advance of a patient's scheduled appointment.

4 Administer the injections

Alternate Site of Administration (ASA)
The administration of specialty injectables at an alternate site may be a more convenient option for you and/or your patients. When utilized, the ASA will conduct the benefits verification, acquire the medication, and collect the co-pay or coinsurance instead of your practice.

The patient pays any drug-related co-pays or coinsurance directly to the specialty pharmacy

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

- The concomitant use of CABENUVA and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)
- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval
- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

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Pathways to prepare your practice for CABENUVA

When you prescribe CABENUVA, you have flexibility in how you access and acquire treatment for patients, whether you are working with a specialty distributor (Buy & Bill) or a specialty pharmacy.

ViiVConnect-supported pathway

- Offers practices tools, resources, and individual assistance to help prescribers implement and manage the processes for CABENUVA, including:
  - Tailored case management
  - Benefits verification
  - Prior authorization, claims denials, and appeals support
- Access to Field Reimbursement Managers for patient-specific questions

Independently managed pathway

- Offers flexibility, allowing your office to verify benefits and navigate the acquisition process for CABENUVA
- Your Field Reimbursement Manager can provide general support but cannot answer patient-specific questions

To take advantage of the services ViiVConnect offers, you can enroll patients at any time—even after treatment has begun

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with CABENUVA:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly or every-2-month injection dosing schedule because non-adherence could lead to loss of virologic response and development of resistance
- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of CABENUVA when dosed monthly and no later than 2 months after the final injections of CABENUVA when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

ADVERSE REACTIONS

- The most common adverse reactions in adults (incidence ≥2%, all grades) treated with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
- The safety of CABENUVA in adolescents is expected to be similar to adults

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Practice considerations for CABENUVA implementation

Here are some topics your practice should consider when preparing to prescribe CABENUVA.

Logistics

- Consider where the medication will be stored
  - Familiarize your practice with cold-chain shipment processes and prepare sufficient refrigerator space
- Develop a process for tracking or receiving medication in the clinic if one is not already in place
- Ensure payer contracts are up to date and contracts with specialty distributors are in place

Access

- Familiarize your team with prescribing pathways/benefits verification processes
  - Consider nominating an internal partner to support and oversee these processes

Initiating CABENUVA

- Contact your ViiV Healthcare account manager for injection education resources
- Ensure multiple staff members are trained to administer gluteal injections

Billing

- Familiarize yourself and your office staff with both specialty pharmacy and Buy & Bill processes and understand how they can work with your pre-existing billing systems

Questions? Your ViiV Healthcare representatives are available to assist you throughout the implementation process

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

- Refer to the applicable full Prescribing Information for important drug interactions with CABENUVA, VOCABRIA (cabotegravir), or EDURANT (rilpivirine)
- Because CABENUVA is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that are strong inducers of UGT1A1 or UGT1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine
- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

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Are you ready to transform the treatment experience for your patients?

Incorporating specialty injectables like CABENUVA into your practice can provide patients with an alternative to daily oral HIV therapies. Your CABENUVA support team can help jump-start this implementation process in your practice.

Your CABENUVA support team

Territory Account Manager (TAM)

Your TAM is a ViiV representative who is here to answer any product-related questions and support the implementation needs in your office.

Field Reimbursement Manager (FRM)

Your FRM is a ViiV representative who is here to support your office through access, acquisition, billing, and reimbursement.

Access Coordinator (AC)

Your Access Coordinator assists your office and your patients enrolled in ViiVConnect with ViiVConnect patient services.

Where do you begin?

Talk to your ViiV Representative (TAM, FRM, AC) or visit ViiVConnect.com for helpful resources.

Reference: 1. Marlo K. How well are specialty injectable drugs managed? *Biotechnol Healthc.* 2004;1(1):38-43.

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are insufficient human data on the use of CABENUVA during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using CABENUVA during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA. An Antiretroviral Pregnancy Registry has been established
- **Lactation:** The CDC recommends that HIV-1–infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA

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