Specialty pharmacy checklist

Refer to this checklist if your practice will be acquiring prescribed CABENUVA through a specialty pharmacy.

Before the initiation injections*†:

Check the box and indicate the date the task was performed:

- ☐ Confirm your patient's enrollment in ViiVConnect.*† _____
- ☐ Confirm your patient's eligibility for CABENUVA by verifying their benefits. _____
- ☐ Choose a specialty pharmacy from the list at ViiVConnect.com/sp_sd or in the How to Order CABENUVA booklet. _____
- ☐ ViiVConnect will send the injection prescription to the specialty pharmacy on your behalf. _____
- ☐ Schedule CABENUVA shipment date with the specialty pharmacy. _____

Key considerations:

- Be sure to choose a specialty pharmacy from the in-network list on ViiVConnect.com
  - Your patient's insurance may specify which specialty pharmacies you can order from
- Keep your patient's appointment date in mind when scheduling the CABENUVA shipping date with the specialty pharmacy
- If you haven't received any communications from the specialty pharmacy, and your patient's appointment is ≤10 days away, please contact the specialty pharmacy directly

(*Continued on page 2*)

*This checklist is for providers who have chosen to use ViiVConnect support. Enrollment in ViiVConnect is not required for your patients to access their prescribed CABENUVA.

† Prior to initiating CABENUVA, cabotegravir (30-mg) and rilpivirine (25-mg) tablets may be used as an optional oral lead-in for approximately 1 month (at least 28 days). Adherence to the dosing schedule is strongly recommended.

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 throughout and click for full Prescribing Information.

ViiVConnect

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

Specialty pharmacy checklist (cont'd)

After the initiation injections:

- [ ] Collect co-pay for office visit, if applicable. _____
- [ ] Submit claim forms for administration fee and office visit fees to payer, if applicable. _____
  - **Refer to the CABENUVA Reimbursement Guide for relevant codes and examples of forms**
- [ ] For patients enrolled in the CABENUVA Savings Program: after payer reimbursement, submit Explanation of Benefits at ViiVClaims.com for reimbursement of administration fee. _____
- [ ] The specialty pharmacy will contact your patient for approval to ship continuation injections. Patients should be made aware this call is coming and that they need to answer in order to prevent delays. _____
- [ ] The specialty pharmacy will contact you to schedule shipment dates. _____

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with CABENUVA
- 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
- 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

Please see additional Important Safety Information throughout and click for full Prescribing Information.

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

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

Depressive Disorders:

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

Please see additional Important Safety Information throughout and click for full Prescribing Information.

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

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

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

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:** Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

Please see additional Important Safety Information throughout and click for full Prescribing Information.

ViiVConnect

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