ViiV Injectables

CABENUVA

cabotegravir 200 mg/mL; rilpivirine 300 mg/mL

extended-release injectable suspensions

Access and Reimbursement Guide

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

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with CABENUVA or its components. 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

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

START

CONTENTS

CMS=Centers for Medicare & Medicaid Services.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions: (cont'd)

- 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. Please click for full Prescribing Information for CABENUVA.

ACCESS OVERVIEW

CONDUCTING A BENEFITS VERIFICATION

You can enroll in ViiVConnect Hub Services to have your patient's benefits verified for you, or your office may perform the verification independently.

OPTION 1

ViiVConnect services

Enrolling in ViiVConnect Hub Services provides support for acquiring and administering CABENUVA for practices, including:

- Performance of benefits verifications
- Assistance in navigating product acquisitions

OPTION 2

Independently managed

For practices that prefer to manage the prescribing and acquisition of CABENUVA on their own:

- This option allows your office to conduct benefits verifications and navigate product acquisitions

Benefits verification results include:

- Predetermination
- Acquisition pathway information
- Prior Authorization (PA) requirement(s)

Factors that can affect access and reimbursement

1 Type of payer

Understanding your patient's insurance status and requirements are essential to helping them access their medication as prescribed.

Your patient may have coverage under one of the following payers:

- Private or commercial insurance
- Medicaid and/or Medicare

2 Acquisition pathway

An insurance plan may cover CABENUVA under:

- The medical and/or pharmacy benefit

This information is confirmed during the benefits verification process, which helps determine how CABENUVA will be acquired and reimbursed for your patient.

3 Place of service

Insurance coverage of medications administered by a provider, such as CABENUVA, may vary depending on where the product is administered. Locations include:

- Your office
- A hospital outpatient facility
- An independent clinic
- An Alternative Site of Care (ASOC), such as an infusion clinic

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

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

ViiV Injectables

COVERAGE DECISIONS

PRIOR AUTHORIZATION, EXCEPTION REQUESTS, AND APPEALS

In addition to a prescription for CABENUVA, some payers and formulary decision-makers may require more information. **There are 3 primary categories of requests for additional information:**

1 **Prior Authorization**

2 **Exception requests**

3 **Appeals**

Prior Authorization (PA)

PA is a common payer requirement where providers must submit medical necessity information before coverage is approved for a therapy or service. If the benefits verification shows that your patient's insurance requires a PA for CABENUVA, you will need to prepare the necessary documentation. Since coverage criteria may vary, it is important to review each insurer's specific guidelines.

Tips for submitting a PA

Documentation you may want to include with the required PA form:

- Letter of medical necessity
- Copy of the medical and/or pharmacy benefit insurance card(s) (front and back)
- Patient's history and current condition
- Date and method of diagnosis, including ICD-10-CM code(s)
- Laboratory results and date
- Previous therapies/treatments and response to those interventions
- Summary of professional opinion of the patient's likely prognosis without treatment with CABENUVA
- Use the plan's most recent form

Exception requests

An exception request is a formal request made by a healthcare provider to a payer asking for coverage of a specific medication, treatment, or service that is not typically included in the insurer's plan.

Common types of exception requests

- **Nonformulary exception:** Requesting approval for a medication or treatment not listed in the plan's formulary
- **Step therapy exception:** If the patient cannot use the preferred medication or treatment due to a medical condition or previous treatment failure, a request is made for a different, nonpreferred option
- **PA exception:** When a treatment or service requires prior approval but the provider requests an exception based on the patient's unique needs

These requests are typically reviewed by the insurance company's medical or pharmacy team, and they may be approved or denied based on the submitted documentation and the insurer's policies.

Appeals

An appeal is a process used to challenge a payer's adverse coverage decision when a beneficiary believes they are entitled to benefits. If an exception request or PA is denied, an appeal can be filed to reconsider the decision. The appeal process, whether it's a written explanation or a verbal request, will vary based on the patient's insurance plan.

Tips for submitting an appeal

- Review the denial notice to understand the reason for denial and to identify the appeal process requirements (documentation, time frame, etc)
- Verify the information submitted on your PA form was complete and accurate. If there were clerical errors, resolve and resubmit
- Include any supporting documentation as required by the payer (the denial letter, letter of medical necessity, patient records, etc)
- Ensure you are submitting to the appropriate location

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Post-Injection Reactions: (cont'd)

- 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

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

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

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

ViiV Injectables

COVERAGE DECISIONS

LETTER OF MEDICAL NECESSITY

Some payers and formulary decision-makers may require a letter of medical necessity before authorizing a specific therapy for your patient. See below for a sample letter of medical necessity. You will want to draft this rationale on official letterhead, keeping your recommendation clear, concise, and compelling.

Consider including the following items in a letter of medical necessity:

- Clearly state the rationale for why CABENUVA is appropriate for the patient
- Support the therapy recommendation by citing Prescribing Information, published study data, and clinical guidelines, as appropriate
- Specify if the patient is already on CABENUVA and is clinically stable
- Explain why the formulary-preferred agents, if applicable, are not appropriate
- Outline possible implications if the patient goes without therapy or if the patient is denied access

Sample letter

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Name of health plan]
[Mailing address]
Re: [Patient's Name]
[Plan identification number]
[Date of birth]
[Case identification]

Dear [Contact Name or Department]:

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with [PRODUCT] for [INDICATION]. This letter serves to document that [PRODUCT] for [INDICATION] is appropriate, reasonable, and clinically necessary for [PATIENT]. On behalf of the patient, I am requesting approval for use and subsequent coverage/payments.

[PATIENT NAME]'s laboratory results meet the clinical diagnosis criteria for [DIAGNOSIS].

Summary of Patient's History [Describe the patient's medical condition]

Information that may be helpful to include:

- Patient's diagnosis, history, and current clinical status
- Patient's current or previous antiretroviral therapies attempted
- Rationale for therapy with [PRODUCT] including clinical evidence
- Summary of your professional opinion and factors that led to you recommending [PRODUCT] for [INDICATION]

Based on the above facts, [PRODUCT] is appropriate and reasonable for [PATIENT].

Please consider coverage of [PRODUCT] on [PATIENT NAME]'s behalf and approve use and subsequent payment for [PRODUCT]. Please refer to the enclosed Prescribing Information for [PRODUCT]. If you have any further questions regarding this matter, please do not hesitate to call me at [PROVIDER TELEPHONE NUMBER].

Thank you for your prompt attention to this matter.

Sincerely,

[Provider's name], <DEGREE/CREDENTIALS>
[Provider's NPI]
[Provider's practice name]
[Phone number]
[Fax number]

Enclosures (attach as appropriate): Prescribing Information (PI), clinic notes, labs, and other supporting documentation.

CC: [Medical Director, patient, specialty society, Insurance Commissioner]

Go to viivconnect.com/sampleletter to customize a sample letter based on your patient's medical history and information below.

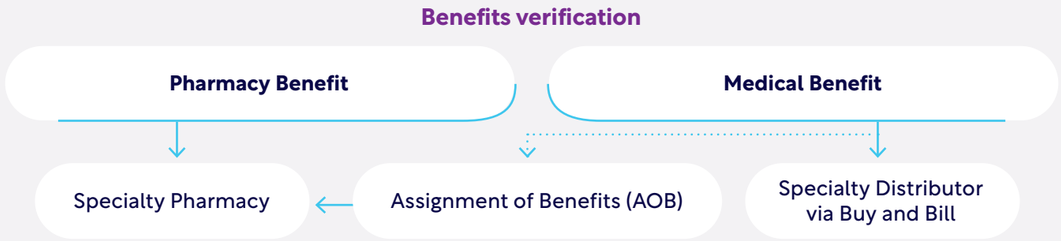
- Some insurance companies may have specific forms that must be completed in order to document medical necessity
- ViiV Healthcare does not guarantee that use of this letter will result in coverage for its products

ACQUISITION PATHWAYS

OVERVIEW

Your patient's insurance plan will determine how CABENUVA is acquired and will be outlined in the summary of benefits.

CABENUVA may be acquired through one of the following pathways:



Pharmacy benefit

If your patient's insurance covers CABENUVA **under the pharmacy benefit**, or if an AOB was performed under the medical benefit, then your office can likely acquire CABENUVA from a **specialty pharmacy.**

See page 5 for more information on acquisition through a specialty pharmacy.

Medical benefit

If your patient's insurance covers CABENUVA **under the medical benefit**, your office can purchase it directly from a **specialty distributor (Buy and Bill)**.

See page 5 for more information on acquisition through a specialty distributor.

Assignment of Benefits (AOB)

In some instances, a specialty pharmacy may be able to bill the patient's medical benefit, also referred to as an AOB. **An AOB is a secondary process used by a payer that will help determine if the ViiV 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. Speak with your Field Reimbursement Manager (FRM) if you would like to learn more about an AOB.

An Alternative Site of Care (ASOC) is a medical facility that can manage the medication acquisition process and administer CABENUVA to your patient.

Visit viivconnect.com/asocinfo for additional information on working with an ASOC.

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, suicide attempt) have been reported with CABENUVA or the individual products
- Promptly evaluate patients with depressive symptoms

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: (cont'd):

- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

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

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

ViiV Injectables

ACQUISITION PATHWAYS

PHARMACY BENEFIT

If your patient's insurance covers CABENUVA under the pharmacy benefit, you may acquire the product through a specialty pharmacy.

Acquiring CABENUVA through the pharmacy benefit:

1. **Submit a prescription.** The payer may dictate which specialty pharmacy can fill the prescription. Review the summary of benefits.
2. **The specialty pharmacy submits the claim to the patient's payer for CABENUVA and collects the copay.** Remind your patient to answer the call from the specialty pharmacy from a number they may not recognize.
3. **The specialty pharmacy ships CABENUVA.** The specialty pharmacy and your practice coordinate shipments to arrive in advance of a patient's scheduled appointment. If you haven't received any communications from the specialty pharmacy, and your patient's appointment is fewer than 10 days away, please contact the specialty pharmacy directly.
4. **Administer the CABENUVA injections.** Schedule subsequent injections.
5. **Submit claims to your patient's insurance company for the office visit and the administration of CABENUVA.** Collect the copay from the patient for the office visit (if applicable). If the patient is enrolled in the ViiVConnect Patient Savings Program, submit the Explanation of Benefits (EOB) to ViiVClaims.com for reimbursement of the administration fee.

Specialty pharmacy network for CABENUVA

Accredo Specialty Pharmacy
Phone: (877) 856-4670
Fax: (888) 302-1028

AHF Pharmacy
Phone: (877) 429-0708
Fax: (833) 814-1322

Avita Pharmacy
Phone: (866) 437-6717
Fax: (803) 358-3034

BioPlus Specialty Pharmacy
Phone: (866) 514-8082
Fax: (800) 269-5493

CenterWell Specialty Pharmacy
Phone: (800) 486-2668
Fax: (877) 405-7940

Coordinated Care Network
Phone: (877) 349-6330
Fax: (412) 825-3525

Curant Health
Phone: (866) 460-8040
Fax: (866) 437-8411

CVS Specialty Pharmacy
Phone: (855) 801-8262
Fax: (866) 279-1993

Mail-Meds Clinical Pharmacy
Phone: (800) 939-2022
Fax: (855) 523-0910

MediLink RxCare Specialty Pharmacy
Phone: (609) 956-1900
Fax: (609) 521-4001

Optum Specialty Pharmacy
Phone: (855) 427-4682
Fax: (877) 342-4596

Walgreens Specialty Pharmacy
Phone: (888) 347-3416
Fax: (877) 231-8302

MEDICAL BENEFIT

If your patient's insurance covers CABENUVA under the medical benefit, you may purchase the product directly from a specialty distributor (Buy and Bill).

Acquiring CABENUVA through the medical benefit:

1. **Order CABENUVA from a specialty distributor.** Your practice buys CABENUVA from the specialty distributor, and the specialty distributor sends directly to your office for inventory.
2. **Schedule and administer CABENUVA.** Coordinate with the patient to schedule their appointment. Pull the product from inventory and administer to the patient. Your practice will need to schedule and confirm your patient's follow-up appointment to ensure their subsequent injection is available and ready to administer in time for their next appointment.
3. **Bill for reimbursement.** Once administered, your practice will bill the patient's insurance for CABENUVA reimbursement and administration services. Your practice is also responsible for collecting any copays or coinsurance for CABENUVA. If applicable, submit payer claim forms for reimbursement of CABENUVA, its administration, and the office visit. After receiving payer reimbursement, if the patient is enrolled in the ViiVConnect Patient Savings Program, submit the EOB to ViiVClaims.com for reimbursement of the administration fee.

Buy and Bill considerations for your practice

Ensure your practice has a contract with the patient's payer, and you are aware of the terms for reimbursement.

Specialty distributor network for CABENUVA

ASD Specialty Healthcare
(800) 746-6273

Besse Medical
(800) 543-2111

Cardinal Health Specialty
Acute: (855) 855-0708
Provider: (877) 453-3972

CuraScript Specialty Distribution
(800) 942-5999

McKesson Medical-Surgical
(800) 446-3008

McKesson Plasma and Biologics
(877) 625-2566

McKesson Specialty
(800) 482-6700

Morris & Dickson Specialty Distribution, LLC
(800) 388-3833

Oncology Supply
(800) 633-7555

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with CABENUVA: (cont'd)

- 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

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

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

ViiV Injectables

BILLING AND CODING

REFERENCE SHEET FOR COMMONLY USED CODES

These codes are only intended to support CABENUVA for the treatment of HIV-1 infection. The codes in this guide are not all inclusive and are for informational purposes only; appropriate codes can vary by patient, setting of care, and payer. The use of the following codes does not guarantee reimbursement.

ICD-10-CM Diagnosis Codes[1]	
B20	Human immunodeficiency virus (HIV) disease
Z21	Asymptomatic HIV infection status

Place of Service Codes[2]	
11	Office
17	Walk-in Retail Health Clinic
19	Off Campus—Outpatient Hospital
22	On Campus—Outpatient Hospital
49	Independent Clinic
71	Public Health Clinic
72	Rural Health Clinic

CPT Code for reporting the injection[2,3]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

ViiV Healthcare does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

HCPCS Code for reporting a provider-administered prescription drug[1,2]	
J0741	Injection, cabotegravir and rilpivirine, 2 mg/3 mg **Billing Units:** • CABENUVA 600-mg/900-mg kit = 300 billing units • CABENUVA 400-mg/600-mg kit = 200 billing units

HCPCS Modifiers[3]	
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

National Drug Codes[2,4]	Billing Units	Description
CABENUVA 600-mg/900-mg kit **10-digit NDC:** 49702-240-15 **11-digit NDC:** 49702-0240-15	ML 6	For use in every-2-month and once-monthly dosing schedules
CABENUVA 400-mg/600-mg kit **10-digit NDC:** 49702-253-15 **11-digit NDC:** 49702-0253-15	ML 4	For use in once-monthly dosing schedule only

ViiV Healthcare does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

CPT=Current Procedural Terminology.

References: 1. National Alliance of State and Territorial AIDS Directors. Cabenuva (cabotegravir & rilpivirine extended-release injections) considerations for AIDS drug assistance programs. March 2022. Accessed May 16, 2025. https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf **2.** National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide.* October 2023. Accessed May 16, 2025. https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf **3.** American Medical Association. CPT® code 96372: injection of drug/substance under skin or into muscle. Accessed May 16, 2025. https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

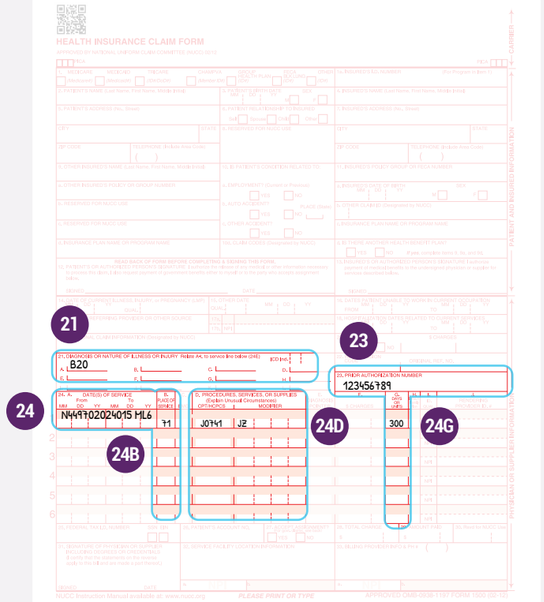
References: 1. American Academy of Professional Coders. HCPCS code for injection, cabotegravir and rilpivirine, 2mg/3mg J0741. Accessed May 16, 2025. https://www.aapc.com/codes/hcpcs-codes/J0741 **2.** National Alliance of State and Territorial AIDS Directors. Cabenuva (cabotegravir & rilpivirine extended-release injections) considerations for AIDS drug assistance programs. March 2022. Accessed May 16, 2025. https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf **3.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **4.** Nevada Medicaid. National drug code (NDC) billing reference. Medicaid.gov website. Updated October 10, 2022. Accessed May 16, 2025. https://www.medicaid.nv.gov/downloads/provider/nv_billing_ndc_reference.pdf

BILLING AND CODING: PROVIDER'S OFFICE

COMPLETE THE CMS 1500 CLAIM FORM

This form can be used for most payers, including Medicaid and commercial. When filling out the form, be sure to use the correct date of service and codes. Submit the form within the plan's designated claim-filing time frame.

Key fields and codes to be used for CABENUVA have been highlighted.



21 Enter the appropriate ICD-10-CM diagnosis code[1]:
- **B20** (HIV disease)
- **Z21** (Asymptomatic HIV infection status)

23 If a Prior Authorization number is required by the payer, enter it here.

24 Enter the NDC qualifier N4, 11-digit NDC number, unit of measure, and quantity in the box[1,2]:
- CABENUVA 600-mg/900-mg kit **N4 49702-0240-15 ML 6**
- CABENUVA 400-mg/600-mg kit **N4 49702-0253-15 ML 4**

24B Enter the appropriate place of service code,[3] for example:
- Office **(code 11)**
- Walk-in Retail Health Clinic **(code 17)**
- Off Campus—Outpatient Hospital **(code 19)**
- On Campus—Outpatient Hospital **(code 22)**
- Independent Clinic **(code 49)**
- Public Health Clinic **(code 71)**
- Rural Health Clinic **(code 72)**

24D Enter the appropriate CPT/HCPCS code: CPT **96372** or HCPCS **J0741**. Add the HCPCS **JZ** Modifier in the right column to indicate zero drug amount was discarded.[4]

NOTE: For 340B customers, the TB Modifier must be used to replace the JG Modifier.[5]

24G Billing units are based on which CABENUVA kit was administered to the patient. There are 2 dosing kits for CABENUVA that are based on the milligrams per injection. Enter the billing units listed below[1]:
- One 400-mg/600-mg kit = **200** billing units (NDC: 49702-253-15)
- One 600-mg/900-mg kit = **300** billing units (NDC: 49702-240-15)

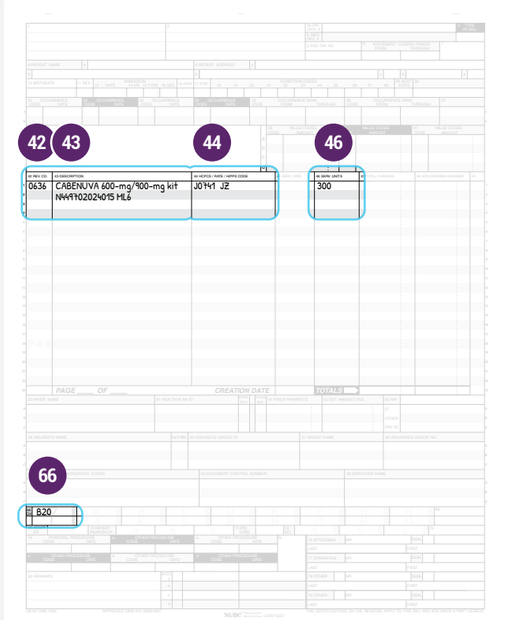
References: 1. National Alliance of State and Territorial AIDS Directors. Cabenuva (cabotegravir & rilpivirine extended-release injections) considerations for AIDS drug assistance programs. March 2022. Accessed May 16, 2025. https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf **2.** Nevada Medicaid. National drug code (NDC) billing reference. Medicaid.gov website. Updated October 10, 2022. Accessed May 16, 2025. https://www.medicaid.nv.gov/downloads/provider/nv_billing_ndc_reference.pdf **3.** National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide.* October 2023. Accessed May 16, 2025. https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf **4.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** Centers for Medicare & Medicaid Services. Revised Part B inflation rebate guidance: use of the 340B modifier. December 14, 2023. Accessed May 16, 2025. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf

BILLING AND CODING: HOSPITAL, NURSING FACILITY, OR OTHER INPATIENT FACILITY

COMPLETE THE CMS 1450/UB-04 CLAIM FORM

This form can be used for most payers, including Medicaid. When completing claim forms, make sure the date of service, billing codes, and billing units are accurate. Submit the form within the plan's designated claim-filing time frame.

Key fields and codes to be used for CABENUVA have been highlighted.



42 Enter revenue code **0636** (drugs that require detailed coding).[1]

43 Include the NDC qualifier N4 followed by the 11-digit NDC, unit of measure, and quantity delivered to the patient[2,3]:
- While the NDC number issued by the FDA is a 10-digit number, most payers require an 11-digit number. To convert to an 11-digit number, place a "0" before the second set of numbers (after the first dash). For example, the 11-digit NDC for the CABENUVA 600-mg/900-mg kit would be: 49702-0240-15. *Confirm all requirements, as they may vary by payer*
- One CABENUVA 600-mg/900-mg kit **N4 49702-0240-15 ML 6**
- One CABENUVA 400-mg/600-mg kit **N4 49702-0253-15 ML 4**

44 Enter the appropriate CPT/HCPCS code: CPT **96372** or HCPCS **J0741**. Add the HCPCS **JZ** Modifier to indicate zero drug amount was discarded.[4]

NOTE: For 340B customers, the TB Modifier must be used to replace the JG Modifier.[5]

46 Billing units are based on which CABENUVA kit was administered to the patient. There are 2 dosing kits for CABENUVA that are based on the milligrams per injection. Enter the billing units listed below[2]:
- One 400-mg/600-mg kit = **200** billing units (NDC: 49702-253-15)
- One 600-mg/900-mg kit = **300** billing units (NDC: 49702-240-15)

66 Enter the appropriate ICD-10-CM diagnosis code[2]:
- **B20** (HIV disease)
- **Z21** (Asymptomatic HIV infection status)

FDA=United States Food and Drug Administration.

References: 1. Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Updated December 26, 2024. Accessed May 16, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913 **2.** National Alliance of State and Territorial AIDS Directors. Cabenuva (cabotegravir & rilpivirine extended-release injections) considerations for AIDS drug assistance programs. March 2022. Accessed May 16, 2025. https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf **3.** Nevada Medicaid. National drug code (NDC) billing reference. Medicaid.gov website. Updated October 10, 2022. Accessed May 16, 2025. https://www.medicaid.nv.gov/downloads/provider/nv_billing_ndc_reference.pdf **4.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** Centers for Medicare & Medicaid Services. Revised Part B inflation rebate guidance: use of the 340B modifier. December 14, 2023. Accessed May 16, 2025. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

- 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

DRUG INTERACTIONS (cont'd)

- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

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

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

ViiV Injectables

ORDERING INFORMATION

PRODUCT INFORMATION

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

Product/Strength	Count
 **600-mg/900-mg Kit** (600-mg/3-mL cabotegravir; 900-mg/3-mL rilpivirine)	2 vials
 **400-mg/600-mg Kit** (400-mg/2-mL cabotegravir; 600-mg/2-mL rilpivirine)	2 vials

Storage and Handling

- Store in the refrigerator at 2 °C to 8 °C (36 °F to 46 °F) in the original carton until ready to use
- Prior to administration, vials should be brought to room temperature (not to exceed 25 °C [77 °F]). Vials may remain in the carton at room temperature for up to 6 hours; do not put back into the refrigerator. If not used within 6 hours, they must be discarded
- Once CABENUVA has been drawn into the syringe, the injection should be administered as soon as possible, but may remain in the syringe for up to 2 hours. The filled syringe should not be placed in the refrigerator. If 2 hours are exceeded, the filled syringe and needle must be discarded
- Do not freeze or mix with other products or diluents

DOSING AND ADMINISTRATION

Category	Relevant information for coverage determinations
Dosing and administration	CABENUVA consists of 2 IM injections administered by a healthcare professional at 2 separate gluteal sites (opposite sides or 2 cm apart) during the same visit. **Every-2-month** **Initiation injections** **Month 1** **The first 2 injections are administered:** 600-mg/3-mL cabotegravir and 900-mg/3-mL rilpivirine. The second set of initiation injections are administered 1 month later. **Month 2** **Month 3** **Continuation injections** **Months 4, 6, and beyond** For duration of treatment, 600-mg/3-mL cabotegravir and 900-mg/3-mL rilpivirine are administered every 2 months. **Once-monthly** **Initiation injections** **Month 1** **The first 2 injections are administered:** 600-mg/3-mL cabotegravir and 900-mg/3-mL rilpivirine. **Continuation injections** **Once monthly starting Month 2** For duration of treatment, 400-mg/2-mL cabotegravir and 600-mg/2-mL rilpivirine are administered every month.
Optional oral lead-in	Prior to initiating treatment with CABENUVA, healthcare professionals may consider using an optional oral lead-in to assess tolerability. Please see the Full Prescribing Information for details.

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

IM=intramuscular.

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

- **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. Please click for full Prescribing Information for CABENUVA.

SERVICES

ViiVCONNECT HUB SERVICES

ViiVConnect Hub services offers support resources to facilitate patient access to CABENUVA. Your office has the flexibility to choose the level of service needed.

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

USING ViiVCONNECT HUB SERVICES

Through ViiVConnect, you can:

- Conduct a benefits verification
- Navigate acquisition pathways (medical benefit, pharmacy benefit, or both)
- Receive patient-specific case management with a single point of contact
- Confirm eligibility and enroll patients in savings support programs
- Identify formulary exceptions, PA requirements, and predeterminations
- Get information on reimbursement claims, denials, and appeals
- Coordinate with specialty pharmacies to facilitate communication with your patients
- Receive patient enrollment status updates and identify missing information

Enroll your patients in ViiVConnect via one of the following options:

Complete a **CABENUVA Enrollment Form** and fax it to 1-844-208-7676

Visit the **ViiVConnect HCP Portal** to enroll your patients electronically and to take advantage of the portal's additional offerings

PATIENT eSIGNATURE

Get your patient's eSignature authorization by scanning the QR code below.

Call a ViiVConnect Access Coordinator

1-844-588-3288

Toll free. Monday–Friday, 8 AM–8 PM (ET).
Language options are available.

ViiV Injectables

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.
Please click for full Prescribing Information for CABENUVA.