Medical Policy:

Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injectable suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.328	March 25, 2024	April 5, 2021

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Cabenuva, a two-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand-transfer inhibitor, and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor, 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 35kg to replace their current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to cabotegravir or rilpivirine.

Length of Authorization

Initial coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Initially 600 mg/900 mg for one dose only followed by 400 mg/600 mg monthly thereafter

Recommended Dosing Schedule with Optional Oral Lead-in or Direct to Injection for Monthly Injection

Drug	Optional Oral Lead-in[a] (at Least 28 Days)	Intramuscular (Gluteal) Initiation Injections (One-Time Dosing)	Intramuscular (Gluteal) Continuation Injections (Once-Monthly Dosing)
	Month (at Least 28 Days) Prior to Starting Injections	Initiate Injections at Month 1[b]	One Month after Initiation Injection and Monthly Onwards
Cabotegravir	30 mg once daily with a meal	600 mg (3 mL)	400 mg (2 mL)
Rilpivirine	25 mg once daily with a meal	900 mg (3 mL)	600 mg (2 mL)

[a] The optional oral therapy should be continued until the day the first injection is administered.

[b] Given on the last day of current antiretroviral therapy or oral lead-in if used.

Recommended Dosing Schedule with Optional Oral Lead-in or Direct to Injection for Every-2-Month Injection

Drug	Optional Oral Lead-in[a] (at Least 28 Days)	Intramuscular (Gluteal) Injections[b]
	Month (at Least 28 Days) Prior to Starting Injections	Initiate Injections[c] at Month 1, Month 2, and then Every 2 Months Onwards (Starting at Month 4)
Cabotegravir	30 mg once daily with a meal	600 mg (3 mL)
Rilpivirine	25 mg once daily with a meal	900 mg (3 mL)

[a] The optional oral therapy should be continued until the day the first injection is administered.

[b] For the every-2-month injection dosing schedule in adults, Initiation Injections are injections administered at Month 1 and Month 2 and Continuation Injections are injections administered every 2 months onwards (starting Month 4).

[c] Given on the last day of current antiretroviral therapy or oral lead-in if used.

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Human Immunodeficiency Virus (HIV), Treatment**
   - A. Patient is ≥ 12 years of age; **AND**
   - B. Patient weighs greater than or equal to 35 kg; **AND**
   - C. The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of HIV infection; **AND**
   - D. Patient has HIV type-1 (HIV-1) infection; **AND**
   - E. Patient has HIV-1 RNA < 50 copies/mL (viral suppression); **AND**
   - F. Prior to initiating Cabenuva **OR** 1 month lead-in with Vocabria (cabotegravir tablets), the patient was treated with a stable regimen (≥ 3 months) of antiretrovirals for HIV-1

II. RENEWAL CRITERIA

Coverage can be renewed based on the following criteria:

1. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include the following: signs or symptoms of hypersensitivity reactions and if hepatotoxicity, marked elevations in transaminases, and psychiatric/depressive symptoms*.; **AND**
2. Patient has HIV-1 RNA < 50 copies/mL (viral suppression)

Limitations/Exclusions

1. Pre-Exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection
2. Co-administration with Antiretrovirals for Human Immunodeficiency Virus (HIV) Treatment

3. Human Immunodeficiency Virus (HIV)-2 Infection

Applicable Procedure Codes

Code	Description
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg

Applicable NDCs

Code	Description
49702-0240-15	Cabenuva (Cabotegravir;Rilpivirine) 600-mg/900-mg Kit
49702-0253-15	Cabenuva (Cabotegravir;Rilpivirine)400-mg/600-mg Kit

ICD-10 Diagnoses

Code	Description
B20	Human immunodeficiency virus (HIV) disease
Z21	Asymptomatic HIV infection status

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/25/2024	Annual Review: Initial Criteria: Human Immunodeficiency Virus (HIV) Updated statement to include “or equal to 35kg”- “Patient weighs greater than or equal to 35 kg” Updated the following statement from “>4 months” to “>3 months”- “Prior to initiating Cabenuva or 1 month lead-in with Vocabria (cabotegravir tablets), the patient was treated with a stable regimen (≥ 3 months) of antiretrovirals for HIV-1” Renewal Criteria: Added: “Patient has HIV-1 RNA < 50 copies/mL (viral suppression)” Added all Limitations and Exclusions.
EmblemHealth & ConnectiCare	7/24/2023	Annual Review: Dosing Limits: added “Initially 600 mg/900 mg for one dose only followed by 400 mg/600 mg monthly thereafter”
EmblemHealth & ConnectiCare	9/22/2022	Updated policy to reflect new FDA labeled indication: *Recommended Optional* Oral Lead-in Dosing instead of mandatory Oral lead in. Added criteria requiring that prior to initiating therapy with “Cabenuva” or 1 month lead-in with Vocabria the patient was treated with a stable regimen (≥ 4 months) of antiretrovirals for HIV-1. Updated age restriction to include adolescents 12 Years of Age and Older and Weighing at Least 35 kg
EmblemHealth & ConnectiCare	4/6/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	4/5/2021	New Medical Policy

References

1. CABENUVA ® injectable suspension [package insert]. Research Triangle Park, NC. ViiV Healthcare. August 2022
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Updated December 18, 2019. Accessed on January 27, 2021.
3. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.