Clinical Policy: Emtricitabine/Tenofovir Alafenamide (Descovy)

Reference Number: CP.PMN.235
Effective Date: 06.01.20
Last Review Date: 05.21
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Emtricitabine/tenofovir alafenamide (Descovy®) is a combination of two nucleoside reverse transcriptase inhibitors (NRTIs).

FDA Approved Indication(s)

Descovy is indicated:

- In combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adults and pediatric patients weighing at least 35 kg
- In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg
- In at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP

Limitation(s) of use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Descovy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**

1. Diagnosis of HIV-1 infection;
2. Descovy is prescribed in combination with other antiretroviral agents for the treatment of HIV-1 infection;
3. Member weighs ≥ 25 kg;
4. If treatment naïve, member must use emtricitabine/tenofovir disoproxil fumarate (generic Truvada®), unless contraindicated, clinically significant adverse effects are experienced, or member has bone/renal co-morbidities or risk factors (*see Appendix D*);

5. Dose does not exceed 200/25 mg (1 tablet) per day.

Approval duration: 12 months

B. Pre-exposure HIV Prophylaxis (must meet all)**:**

1. Member is HIV-negative and has no signs or symptoms of acute HIV infection;
2. Member is considered at high risk for acquiring HIV and meets one of the following (a, b, or c):
   a. Engaging in sexual activity with a HIV-1 infected partner;
   b. Engaging in sexual activity and one or more of the following:
      i. Inconsistent or no condom use;
      ii. Diagnosis of sexually transmitted infections;
      iii. Exchange of sex for commodities;
      iv. Incarceration;
      v. Not in a monogamous partnership;
      vi. Partner of unknown HIV status with any of the preceding risk factors;
   c. Use of illicit injection drugs;
3. Member weighs ≥ 35 kg;
4. Member must use emtricitabine/tenofovir disoproxil fumarate (generic Truvada), unless contraindicated, clinically significant adverse effects are experienced, or member has bone/renal co-morbidities or risk factors (*see Appendix D*);
5. Dose does not exceed 200/25 mg (1 tablet) per day.

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Descovy for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200/25 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HIV: human immunodeficiency virus
PrEP: pre-exposure prophylaxis

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Truvada (emtricitabine/ tenofovir disoproxil fumarate)	HIV-1 Infection: Adults and pediatric patients weighing ≥ 35 kg: 200/300 mg PO QD Pediatric patients weighing between 17 to < 35 kg: 17 kg to < 22 kg: 100/150 mg PO QD 22 kg to < 28 kg: 133/200 mg PO QD 28 kg to < 35 kg: 167/250 mg PO QD PrEP: 200/300 mg PO QD	See regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): HIV-1 PrEP in individuals with unknown or positive HIV-1 status
- Boxed warning (s): post-treatment acute exacerbation of hepatitis b and risk of drug resistance with use of Descovy for HIV-1 PrEP in undiagnosed early HIV-1 infection

Appendix D: General Information

- Tenofovir is available in two forms: tenofovir alafenamide (TAF; found in Descovy) and tenofovir disoproxil fumarate (TDF; found in Truvada). TAF is associated with fewer bone and renal toxicities than TDF, while TDF is associated with lower lipid levels. According to the Department of Health and Human Services guidelines for the use of antiretroviral agents in adults and adolescents with HIV (last updated December 2019), safety, cost, and accessibility are among the factors to consider when choosing between these drugs. One form is not preferred over the other.
- Examples of bone/renal co-morbidities and risk factors include but are not limited to:

- Bone disease: osteoporosis, osteopenia, receiving chronic corticosteroids or other therapies known to decrease bone density (e.g., aromatase inhibitors, androgen deprivation therapy, doxorubicin, cyclophosphamide), frail/underweight
- Renal disease: chronic kidney disease, estimated creatinine clearance < 60 mL/min, albuminuria, family history of kidney disease, diabetes, receiving nephrotoxic medications

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection, PrEP	200/25 mg PO QD	200/25 mg/day

VI. Product Availability

Tablet: 200 mg emtricitabine/25 mg tenofovir alafenamide

VII. References

1. Descovy Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; January 2020. Available at www.descovy.com. Accessed January 12, 2021.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. U.S. Department of Health and Human Services. Available at: https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated December 18, 2019. Accessed January 12, 2021.
3. Centers for Disease Control and Prevention, U.S. Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2017 update. 2017. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Accessed January 12, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per April SDC and prior clinical guidance.	04.27.20	05.20
Added HIM line of business to policy.	08.19.20	
2Q 2021 annual review: no significant changes; specified that the generic form of Truvada should be tried when available; revised "medical justification" to "must use" language; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	01.12.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.