



Louisiana

emtricitabine/tenofovir Branded Products (Descovy[®], Truvada[®])

Policy # 00762

Original Effective Date: 01/01/2022

Current Effective Date: 08/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider emtricitabine/tenofovir alafenamide (Descovy[®])[†] and emtricitabine/tenofovir disoproxil fumarate (Truvada[®])[‡] for the treatment and pre-exposure prophylaxis (PrEP) of Human Immunodeficiency Virus – 1 (HIV-1) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for emtricitabine/tenofovir alafenamide (Descovy) and emtricitabine/tenofovir disoproxil fumarate (Truvada) will be considered when the criteria for the requested drug are met:

- For Descovy 200/25 mg Requests:
 - Patient is stabilized on OR is new to therapy with Descovy for the treatment of Human Immunodeficiency Virus – 1 (HIV-1); OR
 - Patient is requesting Descovy for pre-exposure prophylaxis (PrEP) of HIV-1; AND
 - Patient has tried and failed (e.g., intolerance) GENERIC emtricitabine/tenofovir disoproxil fumarate unless there is clinical evidence or patient history that suggests the use of GENERIC emtricitabine/tenofovir disoproxil fumarate will be ineffective or cause an adverse reaction to the patient; OR
 - Patient has a creatinine clearance less than 60 mL/min; OR

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- Patient has osteoporosis or osteopenia
*(Note: The above patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Descovy 120/15 mg Requests:
 - Patient is stabilized on OR is new to therapy with Descovy for the treatment of Human Immunodeficiency Virus – 1 (HIV-1); AND
 - Patient weighs at least 14 kg to less than 25 kg
- For Truvada Requests:
 - Patient has tried and failed (e.g., intolerance) GENERIC emtricitabine/tenofovir disoproxil fumarate unless there is clinical evidence or patient history that suggests the use of GENERIC emtricitabine/tenofovir disoproxil fumarate will be ineffective or cause an adverse reaction to the patient
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of emtricitabine/tenofovir disoproxil fumarate (Truvada) when the patient has not has tried and failed (e.g., intolerance) GENERIC emtricitabine/tenofovir disoproxil fumarate to be **not medically necessary.****

Based on review of available data, the Company considers the use of Descovy 200/25 mg tablets for PrEP when the patient has not tried and failed (e.g., intolerance) GENERIC emtricitabine/tenofovir disoproxil fumarate OR when the patient's creatinine clearance is not less than 60 mL/min OR when the patient does not have osteoporosis or osteopenia to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of emtricitabine/tenofovir alafenamide (Descovy) 120/15 mg for PrEP OR in patients who do not weigh 14 kg to less than 25 kg to be **investigational.***

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Background/Overview

Descovy and Truvada are each indicated for the treatment and pre-exposure prophylaxis (PrEP) of Human Immunodeficiency Virus – 1 (HIV-1) infection. Descovy is available in two strengths, 200/25 mg and 120/15 mg, in which the 120/15 mg strength is only indicated for those who weigh 14 kg to less than 25 kg. Both strengths are indicated for the treatment of HIV-1 infection, but only the 200/25 mg strength carries the additional indication for PrEP. For the treatment of HIV-1 infection, these products need to be used in combination with other antiretroviral agents. For PrEP, these agents can be used alone. For PrEP, Descovy was shown to be non-inferior to Truvada in clinical trials. Truvada has a generic equivalent available, which provides an economically advantageous, yet equally effective, option for therapy. It should be noted that Truvada and its generic are not recommended in HIV-1 uninfected individuals with a creatinine clearance below 60 mL/min. Truvada and its generic also carry a warning for decreases in bone mineral density. In these two instances, Descovy may be a more appropriate option for PrEP.

Human Immunodeficiency Virus-1 (HIV-1)

Human Immunodeficiency Virus-1 (HIV-1) is a virus that attacks the cells of the body's immune system. This makes HIV-1 infected individuals more susceptible to other infections and diseases. If left untreated, it can lead to acquired immunodeficiency syndrome (AIDS). The treatment of HIV-1 infection includes antiretroviral therapy, which slows down the replication of the HIV-1. In 2012, Truvada was the first drug approved by the FDA for pre-exposure prophylaxis (PrEP) of HIV-1. Descovy gained a similar indication in 2019.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Descovy is indicated, in combination with other antiretroviral agents, for the treatment of Human Immunodeficiency Virus-1 (HIV-1) infection in adults and pediatric patients weighing at least 35 kg. Descovy is also indicated, 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 14 kg and less than 35 kg. Descovy also carries an indication for pre-exposure prophylaxis (PrEP) in at-risk adults and adolescents weighing at least 35 kg to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex.

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Truvada is indicated, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg. Truvada is also indicated for PrEP in at-risk adults and adolescents weighing at least 35 kg to reduce the risk of sexually acquired HIV-1 infection.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Given that Truvada has a generic equivalent, which contains the same active ingredients as Truvada and can be substituted for and provide the same clinical benefit as brand Truvada, this section of the policy will focus on pre-exposure prophylaxis (PrEP) trials for both Descovy and Truvada. These trials demonstrate the efficacy of both Descovy and Truvada in PrEP as well as Descovy's non-inferiority to Truvada.

Descovy – PrEP

The efficacy and safety of Descovy to reduce the risk of acquiring HIV-1 infection were evaluated in a randomized, double-blind multinational trial (DISCOVER) in HIV-seronegative men (N=5,262) or transgender women (N=73) who have sex with men and are at risk of HIV-1 infection, comparing once daily Descovy (N=2,670) to Truvada (FTC/TDF 200 mg/300 mg; N=2,665). Evidence of risk behavior at entry into the trial included at least one of the following: two or more unique condomless anal sex partners in the past 12 weeks or a diagnosis of rectal gonorrhea/chlamydia or syphilis in the past 24 weeks. At baseline, 897 participants (17%) reported receiving Truvada for pre-exposure prophylaxis (PrEP). At weeks 4, 12, and every 12 weeks thereafter, all participants received local standard of care HIV-1 prevention services, including HIV-1 testing, evaluation of adherence, safety evaluations, risk-reduction counseling, condoms, management of sexually transmitted infections, and assessment of sexual behavior. Trial participants maintained a high risk of sexual HIV-1 acquisition, with high rates of rectal gonorrhea (Descovy, 24%; Truvada, 25%), rectal chlamydia (Descovy, 30%; Truvada, 31%), and syphilis (14% in both treatment groups) during the trial. The primary outcome was the incidence of documented HIV-1 infection per 100 person-years in

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participants randomized to Descovy and Truvada (with a minimum follow-up of 48 weeks and at least 50% of participants having 96 weeks of follow-up). Descovy was non-inferior to Truvada in reducing the risk of acquiring HIV-1 infection [0.16 HIV-1 infections per 100 person years vs. 0.34 HIV-1 infections per 100 years for Descovy and Truvada, respectively; Rate Ratio 0.468, 95% CI (0.19, 1.15)]. The results were similar across the subgroups of age, race, gender identity, and baseline Truvada for PrEP use. For both Descovy and Truvada, efficacy was therefore strongly correlated to adherence to daily dosing.

Truvada-PrEP

The iPrEx trial was a randomized, double-blind, placebo-controlled multinational study evaluating Truvada in 2,499 HIV-seronegative men or transgender women who have sex with men and with evidence of high-risk behavior for HIV-1 infection. Evidence of high-risk behavior included any one of the following reported to have occurred up to six months prior to study screening: no condom use during anal intercourse with an HIV-1 positive partner or a partner of unknown HIV status; anal intercourse with more than 3 sex partners; exchange of money, gifts, shelter, or drugs for anal sex; sex with male partner and diagnosis of sexually transmitted infection; no consistent use of condoms with sex partner known to be HIV-1 positive.

All subjects received monthly HIV-1 testing, risk-reduction counseling, condoms, and management of sexually transmitted infections. Of the 2,499 enrolled subjects, 1,251 received Truvada and 1,248 received placebo. Subjects were followed for 4,237 person-years. The primary outcome measure was the incidence of documented HIV seroconversion. At the end of treatment, emergent HIV-1 seroconversion was observed in 131 subjects, of which 48 occurred in the Truvada group and 83 occurred in the placebo group, indicating a 42% (95% CI: 18–60%) reduction in risk. Risk reduction was found to be higher (53%; 95% CI: 34–72%) among subjects who reported previous unprotected anal intercourse (URAI) at screening (732 and 753 subjects reported URAI within the last 12 weeks at screening in the Truvada and placebo groups, respectively). Efficacy was therefore strongly correlated with adherence.

The Partners PrEP trial was a randomized, double-blind, placebo-controlled 3-arm trial conducted in 4,758 HIV-1 serodiscordant heterosexual couples in Kenya and Uganda to evaluate the efficacy and safety of tenofovir disoproxil fumarate, TDF, (N=1,589) and Truvada (N=1,583) versus (parallel comparison) placebo (N=1,586) in preventing HIV-1 acquisition by the uninfected partner. All uninfected partner subjects received monthly HIV-1 testing, evaluation of adherence, assessment of

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sexual behavior, and safety evaluations. Women were also tested monthly for pregnancy. Women who became pregnant during the trial had study drug interrupted for the duration of the pregnancy and while breastfeeding. Following 7,827 person-years of follow-up, 82 emergent HIV-1 seroconversions were reported, with an overall observed seroincidence rate of 1.05 per 100 person-years. Of the 82 seroconversions, 13 and 52 occurred in partner subjects randomized to Truvada and placebo, respectively. Two of the 13 seroconversions in the Truvada arm and 3 of the 52 seroconversions in the placebo arm occurred in women during treatment interruptions for pregnancy. The risk reduction for Truvada relative to placebo was 75% (95% CI: 55–87%). Efficacy was strongly correlated with adherence.

References

1. Truvada [package insert]. Gilead Sciences. Foster City, California. Updated June 2020.
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4. www.fda.gov/drugs/generic-drugs/generic-drug-facts. Accessed September 2021.
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6. www.cdc.gov/hiv/basics/prep.html. Accessed September 2021.

Policy History

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10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. New policy.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Updated the original Descovy criteria to reflect that it is now for the 200/25 mg strength. Added a separate section and patient selection criteria for Descovy 120/15 mg. Updated background information to mention the two different strengths of Descovy.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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07/02/2024 Medical Policy Committee review

07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2025

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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