UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1289-7
Program	Prior Authorization/Regulatory
Medication	HIV Pre-exposure Prophylaxis (PrEP) Zero Dollar Cost Share – generic tenofovir disoproxil fumarate 300 mg
P&T Approval Date	11/2019, 8/2020, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.[1]

Once-daily oral treatment with emtricitabine/tenofovir disoproxil fumarate is approved by the US Food and Drug Administration (FDA) for use as PrEP in persons at risk of sexual acquisition of HIV infection. Several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs.[1-3]

This program is designed to meet Health Care Reform requirements which require coverage of effective antiretroviral therapy, which includes tenofovir disoproxil fumarate at zero-dollar cost share if being used for PrEP and criteria are met.

2. Coverage Criteria:

A. **Upon request, coverage at zero-dollar cost share** of generic tenofovir disoproxil fumarate 300 mg will be approved based on **both** of the following criteria:

1. Member is taking generic tenofovir disoproxil fumarate 300 mg as effective antiretroviral therapy for PrEP

-AND-

2. Generic tenofovir disoproxil fumarate 300 mg will be used as part of a comprehensive prevention strategy including other prevention measures

Authorization will be issued for zero copay with deductible bypass for 12 months. If zero-dollar cost share criteria are not met the requested drug will default to standard plan coverage.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10)

and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Requests for Descovy will be reviewed using the Descovy Medical Necessity criteria.

4. References:

1. U.S. Preventive Services Task Force Final Recommendation Statement *Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-exposure Prophylaxis* https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#consider. Accessed July 26, 2024.
2. US Public Health Service Pre-exposure Prophylaxis For The Prevention Of HIV Infection In The United States – 2021 Update – A Clinical Practice Guideline https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf Accessed July 26, 2024.
3. Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc; April 2024.

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Change Control	
Date	Change
11/2019	New program.
8/2020	Added criteria for brand Truvada based on generic launch.
9/2020	Removed brand Truvada as this is a non HCR drug.
9/2021	Annual review with no changes. Updated references.
9/2022	Annual review with no changes to criteria. Added that coverage is provided “upon request” and updated references.
9/2023	Annual review with no changes. Updated references.
9/2024	Annual review with no changes. Updated references.