



SmartPA Criteria Proposal

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| Drug/Drug Class: | PrEP Fiscal Edit |
| First Implementation Date: | April 30, 2020 |
| Revised Date: | N/A |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria |

Executive Summary

Purpose: Ensure appropriate utilization and control of agents used for PrEP

Why Issue Selected: In his State of the Union Address on February 5, 2019, President Donald J. Trump announced a goal to end the HIV epidemic in the United States within 10 years. The new initiative, named Ending the HIV Epidemic: A Plan for America, seeks to reduce the number of new HIV infections in the United States by 75 percent within five years, and then by at least 90 percent within 10 years, for an estimated 250,000 total HIV infections averted. Pre-exposure prophylaxis (PrEP), a once daily oral regimen antiretroviral therapy, has proven to be highly effective in preventing HIV infection for individuals at high risk, reducing the risk of acquiring HIV by up to 97 percent. The US Preventative Services Task Force (USPSTF) published their recommendations on PrEP in June of 2019, stating persons at high risk of HIV acquisition be offered PrEP with effective antiretroviral therapy. Currently, only an approximate 200,000 of an estimated 1.1 million Americans who are at risk for HIV currently receive PrEP. At this time, 2 agents are FDA approved for use as PrEP - Truvada® (emtricitabine and tenofovir disoproxil fumarate) and Descovy® (emtricitabine and tenofovir alafenamide). Truvada was the first medication approved for PrEP and is expected to be available as a generic product as early as September of 2020, with a significant coinciding drop in cost after 6 months of generic exclusivity. Descovy was FDA approved for PrEP on October 3, 2019. Very similar to Truvada, Descovy contains a different tenofovir prodrug, tenofovir alafenamide, and is associated with fewer adverse reactions. MO HealthNet desires to provide PrEP to all qualifying participants, and as such, it is fiscally advantageous for MO HealthNet to establish guidelines for PrEP therapy. This edit will apply only to participants being treated for PrEP and will not affect participants being treated for HIV infection.

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Fiscal Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Agents used for PrEP
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For treatment of HIV: Please see HIV Reference List
- For use for PrEP:
 - Claim is for Truvada **OR**
 - Clinical consultant review required for Descovy

Denial Criteria

- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results:

Progress Notes:

MedWatch Form:

Other:

Disposition of Edit

Denial: Exception code "0683" (Fiscal Edit)
Rule Type: PD

Default Approval Period

1 year

References

- TRUVADA® (emtricitabine and tenofovir disoproxil fumarate) tablets, [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2018.
- DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2019.
- U.S. Department of Health & Human Services. What is 'Ending the HIV Epidemic: A Plan for America'?. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed December 5, 2019.
- Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. U.S. Preventive Services Task Force. July 2019. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>
- IPD Analytics. Rx Insights: Infectious Disease. HIV – Update on Treatment Management. November 2019.
- IPD Analytics. Infectious Disease: HIV. Accessed December 5, 2019.

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