

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antiretrovirals, Treatment Reference Product List
<b>First Implementation Date:</b>	April 2, 2020
<b>Revised Date:</b>	December 17, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** To implement a state-specific open access reference product list.

**Why Issue Selected:** In his State of the Union Address on February 5, 2019, President Donald J. Trump announced a goal to end the human immunodeficiency virus (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.

Nearly 40,000 Americans become infected with HIV each year with approximately 500 of those individuals being from the state of Missouri. As of 2018, roughly 13,000 Missourians were living with HIV. The Missouri Department of Health and Senior Services has a broad array of programs and services to help meet the needs of individuals and communities affected by HIV/AIDS. These programs focus on preventing the spread of HIV, counseling and testing persons at high risk, and caring for persons living with the disease. Through strong partnerships consisting of federal, state and local government agencies, and community-based organizations and volunteers, the state of Missouri is actively engaged in ending the HIV epidemic. MO HealthNet desires to provide antiretroviral therapy to all qualifying participants.

**Program-Specific Information:**

Reference Products	Non-Reference Products
<ul style="list-style-type: none"> <li>• Abacavir</li> <li>• Abacavir/Lamivudine</li> <li>• Atazanavir</li> <li>• Atripla® (Gilead Sciences, Inc.)</li> <li>• Cimduo™ (Mylan Specialty L.P.)</li> <li>• Complera® (Gilead Sciences, Inc.)</li> <li>• Delstrigo™ (Merck Sharp &amp; Dohme Corp.)</li> <li>• <b>Dovato® (ViiV Healthcare Company)</b></li> <li>• Edurant® (Janssen Products, LP)</li> <li>• Efavirenz</li> <li>• <b>Emtricitabine</b></li> <li>• Evotaz™ (E.R. Squibb &amp; Sons, LLC)</li> <li>• Isentress® (Merck Sharp &amp; Dohme Corp.)</li> <li>• Isentress® HD (Merck Sharp &amp; Dohme Corp.)</li> <li>• Lamivudine</li> <li>• Lamivudine/Zidovudine</li> <li>• Norvir® (AbbVie Inc.)</li> <li>• <b>Pifeltro™ (Merck Sharp &amp; Dohme Corp.)</b></li> <li>• Prezcobix® (Janssen Products, LP)</li> <li>• Prezista® (Janssen Products, LP)</li> <li>• Symfi™ (Mylan Specialty L.P.)</li> <li>• Symfi Lo™ (Mylan Specialty L.P.)</li> <li>• <b>Symtuza™</b></li> <li>• Tenofovir</li> <li>• Tivicay® (ViiV Healthcare Company)</li> <li>• Triumeq® (ViiV Healthcare Company)</li> <li>• <b>Trogarzo™ (Theeratechnologies Inc.)</b></li> <li>• Truvada® (Gilead Sciences, Inc.)</li> <li>• <b>Tybost® (Gilead Sciences, Inc.)</b></li> <li>• Viread® Pwd (Gilead Sciences, Inc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Abacavir/Lamivudine/Zidovudine</li> <li>• Aptivus®</li> <li>• Biktarvy®</li> <li>• Combivir®</li> <li>• Crixivan®</li> <li>• Descovy®</li> <li>• Didanosine</li> <li>• Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate</li> <li>• Efavirenz/Lamivudine/Tenofovir Disoproxil</li> <li>• Emtricitabine/Tenofovir Disoproxil Fumarate</li> <li>• Emtriva®</li> <li>• Epivir®</li> <li>• Epzicom®</li> <li>• Fosamprenavir</li> <li>• Fuzeon®</li> <li>• Genvoya®</li> <li>• Intelence®</li> <li>• Invirase®</li> <li>• Juluca</li> <li>• Kaletra®</li> <li>• Lexiva®</li> <li>• Lopinavir/Ritonavir</li> <li>• Nevirapine</li> <li>• Odefsey®</li> <li>• Rescriptor®</li> <li>• Retrovir®</li> <li>• Reyataz®</li> <li>• Ritonavir</li> <li>• Rukobia</li> <li>• Selzentry®</li> <li>• Stavudine</li> <li>• Stribild®</li> <li>• Sustiva®</li> <li>• Temixys™</li> <li>• Trizivir®</li> <li>• Videx®</li> <li>• Viracept®</li> <li>• Viramune®</li> <li>• Viread® Tabs</li> <li>• Zerit®</li> <li>• Ziagen®</li> <li>• Zidovudine</li> </ul>

**Type of Criteria:**  Increased risk of ADE  
 Appropriate Indications

Reference Drug List  
 Clinical Edit

**Data Sources:**  Only Administrative Databases

Databases + Prescriber-Supplied

*SmartPA Clinical Proposal Form*

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## Setting & Population

- Drug class for review: Antiretrovirals, Treatment
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- For treatment of HIV: Claim is for an antiretroviral product
- For use for PrEP: Please see the PrEP Fiscal Edit

## References

- 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>
- Missouri Department of Health and Senior Services at <https://health.mo.gov/living/healthcondiseases/communicable/hivaids/> Website accessed December 2019.
- Evidence-Based Medicine and Fiscal Analysis: "HIV Antivirals – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; August 2020.
- Evidence-Based Medicine Analysis: "Nucleoside Reverse Transcriptase Inhibitors (NRTIs)", UMKC-DIC; November 2020.