

Reference number(s) 5000-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	
Standard Control - Choice (SCCF)	
Preferred Drug Plan Design (PDPD)	
Advanced Control Specialty (ACSF)	
Advanced Control Specialty - Choice (ACSCF)	
Managed Medicaid Template (MMT)	
Marketplace (MF)	
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	
Aetna Individual Lives (IVL)	
Value (VF)	
New to Market (NTM)	

Formulary	Applies
Standard Formulary Chart (SFC)	V
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	
Advanced Control Specialty Formulary Chart (ACSFC)	V
Value Formulary Chart (VFC)	
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Combined Benefit Medical Specialty (CBMS)	
Medical Benefit: Managed Medicaid (MMMB)	
Medicare Part B	
Medicare Part B: Advanced Biosimilars First	

Exceptions Criteria Human Immunodeficiency Virus (HIV) Truvada

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Formulary Chart (SFC) and Advanced Control Specialty Formulary Chart (ACSFC).

Plan Design Summary

This program applies to the human immunodeficiency virus (HIV) products specified in this document. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Specialty Exceptions HIV Truvada SFC-ACSFC 5000-D P2025b.docx

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Table. HIV Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	 abacavir-lamivudine (generic) Cimduo (lamivudine and tenofovir disoproxil fumarate) Descovy (emtricitabine and tenofovir alafenamide) emtricitabine-tenofovir disoproxil fumarate (generic) lamivudine-zidovudine (generic)
Target	Truvada (emtricitabine and tenofovir disoproxil fumarate)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when both of the following criteria are met:

- The member has had a documented intolerable adverse event to the preferred product, generic emtricitabine-tenofovir disoproxil fumarate, and the adverse event was not an expected adverse event attributed to any of the active ingredients as described in the prescribing information.
- Member meets either of the following criteria:
 - For the treatment of HIV-1 infection, the member has a documented inadequate response, intolerable adverse event, or has a contraindication to at least two other preferred products.
 - For pre-exposure prophylaxis (PrEP), the member has a documented intolerable adverse event to Descovy, unless the member is at risk for exposure from receptive vaginal sex.

References

- 1. Abacavir and lamivudine tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2022.
- 2. Cimduo [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2021.
- 3. Descovy [package insert]. Foster City, CA: Gilead Sciences, Inc.; January 2022.
- 4. Emtricitabine and tenofovir disoproxil fumarate tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2024.
- 5. Lamivudine and zidovudine tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2022.

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6. Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2024.

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