SmartPA Criteria Proposal

Drug/Drug Class:	Antiretroviral Therapy (ART) PDL Edit
First Implementation Date:	April 7, 2022
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Human immunodeficiency virus (HIV) is a blood-borne virus that attacks the body's immune system and, if left untreated, can lead to acquired immunodeficiency syndrome (AIDS). HIV is typically transmitted via sexual intercourse, sharing intravenous drug equipment, and mother-to-child transmission. The Centers for Disease Control and Prevention (CDC) classifies HIV infection into 3 stages: Stage 1 (Acute HIV Infection), Stage 2 (Chronic HIV Infection), and Stage 3 (AIDS). Signs and symptoms can present at any of the stages of HIV infection and may include fever, malaise, rash, lymphadenopathy, and severe infections and/or opportunistic malignancies. By the end of 2016, there were an estimated 1.1 million people aged 13 years and older infected with HIV in the United States (U.S.). This includes an estimated 162,500 people who were undiagnosed. According to the 2020 CDC HIV surveillance report, from 2016 to 2020 the annual number and rate of diagnoses of HIV infection in the U.S. decreased marginally each year. However, in 2020, the rate of new diagnoses dropped by 17% to a total of 30,635 patients, likely due to the onset of the COVID19 pandemic.

Antiretroviral therapy was first introduced in 1987 for the treatment of HIV infection. Treatment has drastically improved since and combination ART has greatly reduced HIV-associated morbidity and mortality. Patients currently living with HIV without other significant comorbidities and who are receiving treatment can have life expectancies approaching that of the general population. ART is also effective at preventing HIV transmission in patients who are at higher risk of being exposed to HIV through sexual contact or injection drug use. The U.S. Department of Health and Human Services (DHHS) published updated guidelines in 2021 which recommend combination regimens for people living with HIV infection.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Group A	
Preferred Agents	**Non-Preferred Agents**
• Biktarvy® • Odefsey® • Tivicay® • Tivicay PD® • Triumeq® • **Triumeq PD®**	

Group B	
Single Tablet Regimens (STR)	
Preferred Agents	**Non-Preferred Agents**
• Complera® • Delstrigo® • Dovato® • Efavirenz/Emtricitabine/Tenofovir disoproxil (gen Atripla®) • Genvoya® • Stribild® • Symfi® • Symfi Lo®	• Abacavir/Lamivudine/Zidovudine (gen Trizivir®) • Atripla® • Efavirenz/Tenofovir disoproxil/ Lamivudine (gen Symfi Lo®) • Efavirenz/Tenofovir disoproxil/ Lamivudine (gen Symfi®) • Juluca® • Symtuza® • Trizivir®
Non-Single Tablet Regimens (Non-STR)	
Preferred Agents	**Non-Preferred Agents**
• Abacavir • Abacavir/Lamivudine (gen Epzicom®) • Atazanavir Caps • Edurant® • Efavirenz • Emtricitabine Caps • Emtriva® Soln • Evotaz® • Isentress® • Lamivudine • Lamivudine/Zidovudine (gen Combivir®) • Norvir® **powder packet/solution** • Pifeltro® • Prezcobix® • Prezista® • **Ritonavir Tabs** • Tenofovir Tabs • Tybost® • Viread® Pwd	• Aptivus® • Cabenuva® • **Cabotegravir Vial** • Cimduo® • Combivir® • Crixivan® • Didanosine DR Caps • Emtriva® Caps • Epivir® • Epzicom® • Etravirine Tabs • Fosamprenavir Tabs • Fuzeon® • Intelence® • Invirase® • Kaletra® • Lexiva® • Lopinavir/Ritonavir (gen Kaletra®) • Maraviroc • Nevirapine • **Norvir® Tabs** • Rescriptor® • Retrovir® • Reyataz® • **Rilpivirine Vial** • Rukobia® • Selzentry® • Stavudine Caps • Sustiva®

	• Temixys® • Trogarzo® • Viracept® • Viramune® • Viread® Tabs • Ziagen® • Zidovudine
Group C	
Preferred Agents	**Non-Preferred Agents**
• Emtricitabine/Tenofovir disoproxil (gen Truvada®)	• **Apretude** • Descovy® • Truvada®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Appropriate Indications** ☒ **Preferred Drug List** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Antiretroviral Therapy (ART) Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

Initial Approval

- Participants will be able to access any antiretroviral drug for the treatment of HIV that they currently utilize and on which they are stable or that they have successfully utilized previously, excluding those agents in Group C. For more information on Group C non-preferred agents approval criteria please see below.
- Claims for an agent in Group A do not require prior authorization
- Claim is for an agent in Group B
  - For preferred agents: failure to achieve desired therapeutic outcomes with trial on 1 Group A agent
  - For non-preferred STR agents: failure to achieve desired therapeutic outcomes with trial on 1 Group A agent and 1 preferred Group B STR agent
  - For non-preferred non-STR agents: failure to achieve desired therapeutic outcomes with trial on 1 Group A agent and 1 preferred Group B agent
  - For liquid formulations of zidovudine, nevirapine, and lopinavir/ritonavir: participant is < 10 years of age
  - For Juluca: participant has documented diagnosis of chronic kidney disease stage 3, 4, or 5
  - For Cabenuva:
    - Participant is aged ≥ **12 years** **AND**
    - Dosage regimen is for every two-month administration **AND**
    - Documentation that participant is virologically suppressed (HIV-1 RNA < 50 copies/mL) **AND**
    - Documented compliance to oral ART regimen for at least 3 months **OR**
    - Documented inability to swallow tablets
  - **For Viread: participant has documented diagnosis of hepatitis B infection.**
- Claim is for an agent in Group C
  - Claim for generic Truvada does not require prior authorization
  - For brand Truvada: documented allergy to generic Truvada
  - **For Apretude:**
    - **Documentation of medical necessity (examples include ADE/ADR to gen Truvada or renal insufficiency) AND**

        - **Participant must have a negative test for HIV within one month before initiating therapy**
    - For Descovy: documentation of medical necessity (examples include ADE/ADR to gen Truvada, renal insufficiency, or osteoporosis)

Continuation of Therapy

- Initial Prior Authorization for Cabenuva is 6 months, continued prior authorization will be for 12 months based on:
    - Documented adherence to Cabenuva therapy **AND**
    - Documented continued virologic suppression
- **Initial Prior Authorization for Apretude is 6 months, continued prior authorization will be for 12 months based on:**
    - **Documented adherence to therapy: Compliance is important, and non-compliance increases the risk for drug resistance. Therefore, if a participant misses one of the first three doses of initiation no additional prior authorization to continue will be granted. In addition, if a participant misses two doses in the first year of therapy no additional prior authorization to continue will be granted.**
    - **Participant must be tested for HIV before requesting prior authorization to continue on Apretude. A positive test for HIV during PrEP treatment will result in termination of prior authorization.**

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Cabenuva:
    - History of prior virologic failure **OR**
    - Dosage regimen is for monthly administration
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0160” (PDL Edit)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: ANTI-INFECTIVES: Antiretroviral Therapy: Groups A, B, C”, Gainwell Technologies; Last updated October 3, 2022.
- Evidence-Based Medicine Analysis: “HIV Antiretrovirals”, UMKC-DIC; October 2022.
- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed November 2022.

- IPD Analytics. Rx Insights: Infectious Disease. HIV – Update on Treatment Management. November 2019.
- Centers for Disease Control and Prevention. HIV Surveillance Report, 2021; vol. 33. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published December 2021. Accessed November 2022.
- Gilroy, S. HIV Infection and AIDS. Medscape. HIV Infection and AIDS: Practice Essentials, Background, Pathophysiology (medscape.com). Accessed November 2022.