UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3114-3
Program	Step Therapy
Medications	Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), efavirenz/emtricitabine/tenofovir disoproxil fumarate (generic Atripla)
P&T Approval Date	9/2018, 3/2020, 3/2021
Effective Date	5/1/2021; Oxford only: 5/1/2021

1. Background:

This program requires the provider to validate that the member is not an appropriate candidate for any of the following before providing coverage for Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate): Dovato (dolutegravir/lamivudine), Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate), Triumeq (abacavir/dolutegravir/lamivudine), Isentress/Isentress HD (raltegravir) plus Cimduo (lamivudine/tenofovir disoproxil fumarate), Tivicay (dolutegravir) plus Cimduo (lamivudine/tenofovir disoproxil fumarate), or Juluca (dolutegravir/rilpivirine).

For the treatment of HIV, antiretroviral regimens generally consist of three drugs –a two drug nucleoside reverse transcriptase inhibitor (NRTI) backbone in combination with a third drug from one of the following classes: integrase strand transfer inhibitor (INSTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), or protease inhibitor (PI) with a pharmacokinetic (PK) enhancer. Data also support the use of the two-drug regimen, dolutegravir plus lamivudine, for initial treatment. Based on improved virologic outcomes and tolerability, INSTIs are recommended as first-line treatment options in most patients.[1]

Atripla is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg.[2]

2. Coverage Criteria[a]:

A. HIV

1. **Atripla or generic Atripla** will be approved based on **both** of the following:

   a. Diagnosis of HIV

   -AND-

   b. **One** of the following:

      (1) If the request is for generic Atripla **one** of the following:

         (a) Patient is not an appropriate candidate for any of the following

treatment regimens:

- Symfi, Symfi Lo, or generic equivalent (efavirenz/lamivudine/tenofovir disoproxil)
- Triumeq (abacavir/dolutegravir/lamivudine)
- Isentress/Isentress HD (raltegravir) plus Cimduo (lamivudine/tenofovir disoproxil)
- Tivicay (dolutegravir) plus Cimduo (lamivudine/tenofovir disoproxil)
- Juluca (dolutegravir/rilpivirine)
- Dovato (dolutegravir/lamivudine)

-OR-

(b) Patient is currently on generic Atripla and the provider attests that switching therapy would be clinically inappropriate

-OR-

(2) If the request is for brand Atripla approval will be based on the following:

(a) Patient has experienced intolerance or adverse event to efavirenz/emtricitabine/tenofovir disoproxil fumarate (generic Atripla)

Authorization will be issued for 12 months.

B. <u>Post-Exposure Prophylaxis</u>

1. **Atripla or generic Atripla** will be approved based on the following:

   a. Diagnosis of post-exposure prophylaxis

Authorization will be issued for 4 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

Supply limits may be in place.

4. References:

1. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Available at: https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed March 2021.
2. Atripla [package insert]. Foster City, CA. Gilead; October 2019.

Program	Step Therapy – Atripla (efavirenz/emtricitabine/tenofovir disoproxil)
Change Control	
9/2018	New program
3/2020	Annual review. Added Dovato to list of medications appropriate for use prior to Atripla.
3/2021	Annual review. Clarification added to Symfi/Symfi Lo to allow generic equivalent. Revised criteria to require use of generic Atripla prior to coverage of brand Atripla.