

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3114-1
Program	Step Therapy
Medications	Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
P&T Approval Date	9/2018
Effective Date	4/1/2019; Oxford only: 4/1/2019

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): 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). 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 12 years of age and older.²

2. Coverage Criteria^a:

<p>A. <u>HIV</u></p> <p>1. Atripla will be approved based on <u>both</u> of the following:</p> <p style="margin-left: 20px;">a. Diagnosis of HIV</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 20px;">b. <u>One</u> of the following:</p> <p style="margin-left: 40px;">(1) Patient is not an appropriate candidate for any of the following treatment regimens:</p> <ul style="list-style-type: none"> • Symfi or Symfi Lo (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)

-OR-

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

Authorization will be issued for 12 months.

B. Post-Exposure Prophylaxis

1. **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 August 3, 2018.
2. Atripla [package insert]. Foster City, CA. Gilead; January 2018.

Program	Step Therapy – Atripla (efavirenz/emtricitabine/tenofovir disoproxil)
Change Control	
9/2018	New program