

Clinical Pharmacy Program Guidelines for Stribild

Program	Prior Authorization
Medication	Stribild [®] (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate)
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

1. Background:

Stribild, a combination of 1 integrase strand transfer inhibitor, 1 pharmacokinetic enhancer, and 2 nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors, is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Stribild. Initiation of Stribild in patients with estimated creatinine clearance below 70 mL per minute is not recommended. Discontinue in patients with estimated creatinine clearance below 50 mL per minute.¹

Triumeq, a combination of dolutegravir (integrase strand transfer inhibitor, abacavir, and lamivudine (both nucleoside analogue reverse transcriptase inhibitors), is indicated for the treatment of HIV-1 infection.³

Both Stribild and Triumeq are equally recommended as initial combination treatment regimens for antiretroviral-naïve patients with HIV-1 infection in the most recent Department of Health and Human Services Adult and Adolescents Treatment Guidelines.⁴

Members currently on Stribild therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. Stribild will be approved on the following criterion:

1. Diagnosis of HIV

-AND-

2. One of the following:

a. Patient has tested positive for the HLA-B*5701 allele

-OR-

b. Patient has pre-existing cardiovascular disease

-OR-

c. Patient has significant risk factors for the development of cardiovascular disease

-OR-

d. Patient has experienced intolerance to Triumeq therapy

-OR-

e. Patient has hepatitis B coinfection

-OR-

f. Patient is currently on Stribild or Genvoya therapy

Authorization will be issued for 12 months.

B. Stribild for Post Exposure Prophylaxis

1. Patient has a diagnosis of post-exposure prophylaxis

Authorization will be issued for 4 weeks.

NOTE: Stribild will pay at the point-of-sale if the patient has a diagnosis of post-exposure prophylaxis.

3. References:

1. Stribild [package insert]. Foster City, CA: Gilead Sciences, Inc.; January 2017.
2. Triumeq [package insert]. Research Triangle Park, NC: ViiV Healthcare; April 2016.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Section accessed March 29, 2017.

Program	Prior Authorization –Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate)
Change Control	
Date	Change
12/2013	New guideline
2/2015	Removed requirement of contraindication or not a suitable candidate for both Atripla and Isentress and replaced with a new requirement that the patient has experienced intolerance to Triumeq therapy. Added the following criteria as alternatives to an intolerance to Triumeq therapy: <ul style="list-style-type: none"> • Tested positive for the HLA-B*5701 allele • Pre-existing cardiovascular disease Significant risk factors for the development of cardiovascular disease
7/2016	Aligning with Employer & Individual on clinical criteria but changed authorization duration from 24 to 12 months; updated policy to new template
2/2017	Updated policy template. Added note about paying at point-of-sale with post-exposure prophylaxis diagnosis.
4/2017	Added HIV diagnosis requirement and review criteria for post-exposure prophylaxis
5/2017	Updated background and references