

## **Clinical Policy: Cobicistat; Elvitegravir; Emtricitabine; Tenofovir Disoproxil Fumarate (Stribild)**

Reference Number: OH.PHAR.PPA.01

Effective Date: 12.2015

Last Review Date: 10.2018

Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

The individual component of Stribild™ include cobicistat, a pharmacokinetic enhancer; elvitegravir, an HIV integrase strand transfer inhibitor; emtricitabine, a nucleoside reverse transcriptase inhibitor or NRTI; tenofovir disoproxil fumarate, an acyclic nucleotide reverse transcriptase inhibitor. Stribild™ is available as a single tablet constituting a complete HIV-1 treatment regimen

### **FDA Approved Indication(s)**

Treatment of HIV-1 infection in adult patients who are naïve or treatment-experienced adults who have been 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

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that [Brand name(s)] [is/are] **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Diagnosis (must meet all)**

1. Diagnosis of HIV-1 infection;
2. Age ≥ 18 years;
3. Prescribed as monotherapy for HIV-1 infection;
4. Treatment naïve OR stable on an antiretroviral regimen for at least 6 months and is virologically suppressed (current HIV-1 RNA <50 copies/mL ); Single-agent redirection;
5. Submission of resistance test (dated within the past 3 months) demonstrating virologic susceptibility to **ALL** of the following components of Stribild: elvitegravir, emtricitabine, and tenofovir;
6. Intolerance or contraindication to Genvoya;

7. Intolerance or contraindication to Triumeq or submission of resistance test (dated within the past 3months) demonstrating virologic resistance to ANY of the following components of Triumeq: abacavir, dolutegravir, and lamivudine;
8. Request does not exceed one tablet per day

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy CP.PMN.53.

**II. Continued Therapy** (must meet all)

- A.** Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- B.** Request does not exceed one tablet per day

**Approval duration: 12 months**

**III. Appendices/General Information**

*Appendix A: Special Instructions*

- Antiretroviral drug resistance testing is recommended prior to initiation of therapy in anti-retroviral treatment naive patients and prior to changing therapy for treatment failure.
- Stribild™ is a complete single tablet regimen indicated for once daily use and should not be used with other HIV-1 medicines
- Stribild™ is classified as FDA pregnancy risk category B. No adequate and well-controlled studies in pregnant women have been conducted.  
HIV-infected mothers are advised by the CDC to avoid breast-feeding. This recommendation applies to women who are receiving Stribild™.

**IV. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Treatment of HIV infection	One tablet PO once daily	One tablet per day

**V. Product Availability**

STRIBILD 150mg-150mg-200mg-300mg Tablet

**VI. References**

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services. Available at <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf> (Accessed November, 2017)

2. Stribild™ [package insert]. Foster City, CA: Gilead Sciences Inc. December 2014.  
[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/stribild/stribild\\_pi.ashx](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/stribild/stribild_pi.ashx) (Accessed November, 2017)  
 Gold Standard, Inc. Stribild™. Clinical Pharmacology [database online]. Available at:  
<http://www.clinicalpharmacology.com>. Accessed: April 23, 2015

**VII. Revisions Log**

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12/2015	12/2015
Annual Review – no changes	09/2016	09/2016
Annual Review – no changes	07/2017	07/2017
Removed requirement to have intolerance/contraindication to Atripla; added requirement to have intolerance/contraindication to Triumeq and Genvoya	12/2017	01/2018
Annual Review – no changes	10/18	10/18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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