MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Stribild™
PAGE: 1 of 4	**REFERENCE NUMBER:** OH.PHAR.PPA.01
EFFECTIVE DATE: 12/2015	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/2015, 09/2016, 07/2017
PRODUCT TYPE: Medicaid	**REVISED:** 12/2017

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Purpose: The purpose of this Clinical Policy is to provide a guide to medical necessity for the use of Stribild.

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.

Brand: elvitegravir-cobicistat-emtricitabine-tenofovir (Stribild™): 150-150-200-300mg tablet

FDA Labeled Indications: 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

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Criteria for Approval:

A. Diagnosis of HIV-1 infection; AND

B. Age ≥ 18 years; AND

C. Treatment naïve OR stable on an antiretroviral regimen for at least 6 months and is virologically suppressed (current HIV-1 RNA <50 copies/mL); AND

D. 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 ; AND

E. Intolerance/contraindication to Genvoya; AND

F. Intolerance/contraindication to Triumeq OR submission of resistance test (dated within the past 3 months) demonstrating virologic resistance to **ANY** of the following components of Triumeq; abacavir, dolutegravir and lamivudine; AND

G. Prescribed as monotherapy for HIV-1 infection; AND

H. Request does not exceed one tablet per day

OR

I. Member is currently receiving Stribild as a monotherapy through a Centene benefit and request does not exceed one tablet per day

Approval: Initial Approval: 12 months

Continued Approval: 12 months

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™.

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 (Accessed November, 2017)
3. Gold Standard, Inc. Stribild™. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed: April 23, 2015.

Revision Log	
Revision	**Date**
Reviewed - no changes	9/2016
Reviewed – no changes	7/2017
Reviewed – changed requirement to have intolerance/contraindication to Atripa to intolerance/contraindication to Triumeq AND Genvoya	12/2017

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

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V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file